

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO ETHICON WAVE 5 CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**DEFENDANTS’ OPPOSITION TO PLAINTIFFS’ MOTION TO LIMIT THE OPINIONS
AND TESTIMONY OF JAIME L. SEPULVEDA-TORO, M.D.**

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, “Defendants”) submit this memorandum and attached exhibits in opposition to Plaintiffs’ motion to limit the opinions and testimony of Jaime L. Sepulveda-Toro, M.D.

Plaintiffs adopt their motion and arguments from Wave 1 in moving to exclude in Wave 5 certain expert testimony of Dr. Sepulveda regarding Ethicon’s mesh devices. Yet the Court already ruled on Plaintiffs’ Wave 1 motion regarding Dr. Sepulveda and rejected nearly all of Plaintiffs’ arguments. *See In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2327, 2016 WL 4536872 (S.D.W. Va. Aug. 30, 2016). The only exceptions to this sweeping denial were Plaintiffs’ arguments regarding Dr. Sepulveda’s testimony on Ethicon’s warnings (which the Court accepted in part) and his testimony on certain scientific studies (which the Court reserved ruling on until trial).¹

¹ The Court did not address Plaintiffs’ attack on Dr. Sepulveda’s opinion that fellow pelvic floor surgeons would know of the FDA’s 2008 Public Health Notice on surgical pelvic mesh or Plaintiffs’ request to exclude his opinion that the TVT-O’s design accounts for anatomical considerations. (Plaintiffs’ Mem. (Dkt. No. 2018) at 7, 14). For the reasons set forth below, Plaintiffs’ arguments here are without merit and should be rejected.

Ethicon is mindful of this Court's warning not to assume that a previous *Daubert* ruling is controlling as the Court may be faced "with a different record". *Id.* at *1. Yet in this case, Plaintiffs do not (and cannot) point to any new opinions or testimony by Dr. Sepulveda that might cause the Court to adopt a different course in Wave 5. Instead, Plaintiffs essentially adopt the same arguments and these should suffer the same fate as in Wave 1. Moreover, their arguments with respect to Dr. Sepulveda's opinions on Ethicon's warnings and brochure if narrowly construed, as the Court framed them in Wave 1, should also be denied as moot. Dr. Sepulveda is not being offered to testify as to the legal standard of what should or should not be included in the relevant IFUs or patient brochures.

Instead, he will testify: (a) as to the risks and complications known by surgeons to be common with pelvic surgeries; (b) that mesh surgery has the same risks and complications with only a few, unique exceptions; and (c) those complications and events unique to mesh are covered by the IFU. Those are the relevant facts under the applicable legal standard, as previously found by this Court. Dr. Sepulveda's extensive research of the scientific literature and experience as a surgeon and instructor qualify him to testify to these facts. This is also consistent with this Court's ruling that urogynecologists, like Dr. Sepulveda, may testify as to specific risks of implanting mesh and whether those risks appeared in the IFU.

For these reasons, as detailed further below, Plaintiffs' motion should be denied.

ARGUMENT

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, 2014 U.S. Dist. LEXIS 92316, at *3-8 (S.D.W. Va. July 8, 2014).

I. Plaintiffs' attempt to preclude Dr. Sepulveda from testifying that the subject devices are safe and effective rests on mischaracterizations of his opinions and testimony.

In challenging the reliability of Dr. Sepulveda's opinions that Gynemesh PS, Prolift, Prosima, TVT, and TVT-O are safe and effective, Plaintiffs distort and mischaracterize his deposition testimony.² Indeed, after reviewing these exact same arguments in Wave 1, the Court held that each were "wholly devoid of merit." *In re: Ethicon*, 2016 WL 4536872, at *3. In so doing, the Court found that:

- Plaintiffs' claim that Dr. Sepulveda agreed with the FDA's classification of Gynemesh PS, Prolift, and Prosima as high risk devices was "based on the plaintiffs' mischaracterization of Dr. Sepulveda-Toro's deposition testimony";
- Plaintiffs' argument that Dr. Sepulveda stopped using these devices was "irrelevant because Dr. Sepulveda-Toro merely stopped using the products because they were not on the market"; and
- Plaintiffs' claim that Dr. Sepulveda could not name at his deposition certain five-year studies on SUI products was "meritless because [his] report includes citations to long-term studies, so it does not matter whether Dr. Sepulveda-Toro could recall the studies during his deposition."

In re: Ethicon, 2016 WL 4536872, at *3.

The facts and arguments here remain unchanged. With the record the same as in Wave 1, Plaintiffs' request to exclude Dr. Sepulveda's opinions that the devices at issue are safe and effective should once again be denied.

II. Dr. Sepulveda may testify regarding the FDA's 2008 Public Health notice.

Dr. Sepulveda's opinion that the FDA's 2008 Public Health Notice on surgical pelvic mesh would have been common knowledge to other pelvic floor surgeons is not, as Plaintiffs claim, "pure conjecture." (Plaintiffs' Mem. (Dkt. No. 2018) at 7). In arguing otherwise, Plaintiffs ignore Dr. Sepulveda's experience as an instructor, memberships in multiple professional societies, and numerous other interactions with fellow clinicians. Although the

² He also has a third general report that addresses TVT, TVT-O, and, in particular, TVT Secur. Although this report contains similar opinions, Plaintiffs do not cite to it or appear to be challenging it.

Court did not in its Wave 1 ruling specifically address Plaintiffs' argument here, Ethicon respectfully requests that it do so now and reject Plaintiffs' request to exclude this testimony.

Dr. Sepulveda has taught surgeons on polypropylene midurethral slings for numerous years and over 500 physicians have watched him place a midurethral sling in his operating room. (Plaintiffs' Motion, Ex. B at 1-2). He is a member of the American Urogynecologic Society, American Urogynecologic Association, International Urogynecology Association, and the International Continence Society and a fellow of the American College of Obstetrics and Gynecology and the American College of Surgeons. (*Id.*). Indeed, as he states in his report, all of "[t]he professional education activities provided the opportunity to exchange knowledge among surgeons." (*Id.* at 18).

As a result, Dr. Sepulveda has interacted for multiple years on a near constant basis with fellow practitioners as both a surgeon and instructor regarding the devices at issue. These experiences uniquely qualify him to say whether the contents of the 2008 Public Health Notice would have been common knowledge to his fellow surgeons. *See Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 156 (1999) (stating that "an expert might draw a conclusion from a set of observations based on extensive and specialized experience"); *Flannery v. Bauermeister*, No. CIV.A. 06-399S, 2008 WL 77723, at *2 (D.R.I. Jan. 4, 2008) (granting summary judgment in part based on testimony from the defendants' experts as to what "is known within the correctional medical community"); *Cruz-Vargas v. R.J. Reynolds Tobacco Co.*, 348 F.3d 271, 277 (1st Cir. 2003) (allowing expert testimony of "common knowledge"); *U.S. v. Articles of Device*, 426 F. Supp. 366, 370 (W.D. Pa. 1977) (FDA offered affidavit in misbranding case) ; *Daiichi Pharm. Co. v. Apotex, Inc.*, 380 F. Supp. 2d 478, 489 (D.N.J. 2005) (relying on expert

testimony regarding what an ordinary person skilled in the art would not have known at the relevant time).

It is also interesting to note that Plaintiffs fail to address his contemporaneous writing on this subject in 2008 at the time of the Public Health Notice, which was produced in this litigation. (*See* 10/22/08 Email (ETH.MESH.07383398-401) (attached as Ex. A)). This writing was also reproduced in its entirety within pages 31-37 of his TVT Secur General Report, which pertains to his IFU opinions, complications, and his activities as an instructor. Upon viewing this documentation, it is clear that Plaintiffs' attempt to preclude Dr. Sepulveda from offering such testimony is disingenuous and should therefore be rejected.

III. Dr. Sepulveda may testify to the adverse event risks known by pelvic floor surgeons and that Ethicon's warnings cover the adverse events said to be unique to mesh.

In its Wave 1 decision on Dr. Sepulveda, the Court distinguished between the types of opinions urogynecologists may offer on Ethicon's IFUs. These physicians, like Dr. Sepulveda, "may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." *See In re Ethicon, Inc.*, 2016 WL 4536872, at *3. Conversely, they "must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU." *Id.* On this basis, the Court precluded Dr. Sepulveda from testifying in Wave 1 cases about "what an IFU should or should not include." *Id.*

Ethicon is not challenging this ruling as Dr. Sepulveda does not intend to opine that Ethicon's IFUs should or should not have included certain risks as a matter of law. So, to the extent that Plaintiffs seek only to preclude him from offering this specific opinion, as the Court's Wave 1 ruling states, their motion should be denied as moot.

In support of their failure-to-warn claims, Plaintiffs offer experts who have identified a host of alleged risks and complications to mesh surgery that they contend do not appear on the

relevant IFUs. In response, Ethicon is offering physicians, like Dr. Sepulveda, to testify as to which of those risks and complications identified by Plaintiffs' experts are known by surgeons to be common with all pelvic surgeries and, conversely, whether those risks and complications that are truly unique to mesh surgery are covered by the IFU.

This testimony is critical to Ethicon's "common knowledge" defense under the applicable legal standard establishing the risks and complications that needed to be included in the IFUs. Moreover, this testimony is consistent with this Court's Wave 1 ruling that urogynecologists may testify about the risks of implanting mesh and whether they are discussed in the IFU. *In re Ethicon, Inc.*, 2016 WL 4542054, at *3. It also is consistent with the Court's ruling in *Huskey v. Ethicon, Inc.*, that Plaintiffs' expert, Dr. Jerry Blaivas, "need not be an expert on product warnings per se" but "[r]ather, as a urologist, Dr. Blaivas is qualified to testify about the risks of implanting the TVT-O and *whether those risks were adequately expressed on the TVT-O's IFU.*" 29 F.Supp.3d 691, 719 (S.D. W. Va. 2014) (emphasis added). Dr. Sepulveda is well-qualified to offer this testimony based on both his extensive experience and research. Also, this is a proper subject for expert testimony as numerous courts have held that experts may testify as to whether certain risks associated with a device are commonly known by foreseeable users.

The legal standard. Dr. Sepulveda's testimony on Defendants' IFUs and warnings is consistent with the governing legal standard and should therefore be admitted in its entirety. The legal principle that controls here is that a device manufacturer's duty to warn of adverse events does not include a duty to warn of risks commonly known to the surgeons who use the device. As stated generally in the RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY §2, cmt. j, a product seller "is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product

users.” *See also* RESTATEMENT (SECOND) OF THE LAW OF TORTS §§388(b), 402A, cmt. j; *Roney v. Gencorp*, 654 F. Supp. 2d 501 (S.D. W. Va. 2009) (adopting “sophisticated user” defense in §388). The test is an objective test that depends on the knowledge of foreseeable users generally, and not on the knowledge of persons whose use is at issue in the particular case. *Johnson v. American Standard, Inc.*, 179 P.3d 905, 914 (Cal. 2008) (sophisticated user “knew or should have known” of the danger).

This limitation on the duty to warn is recognized in medical cases as well. There is no duty to warn of risks commonly known to implanting surgeons. *See Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230 (4th Cir. 1984) (duty to warn only of dangers “not well known to the medical community.”). In fact, the FDA device regulations say that information may be omitted from labeling: “if, but only if, the article is a device for which directions, hazards, warnings and other information are commonly known to practitioners licensed by law to use the device.” 21 C.F.R. §801.109(c) (emphasis added). *See also Wright ex rel. Trust Co. of Kansas v. Abbott Laboratories, Inc.*, 259 F.3d 1226, 1234 (10th Cir. 2001) (drug company had no duty to warn hospital of the danger of stocking different concentrations of saline solution in the same place); *Brown v. Drake-Willock Intern. Ltd.*, 530 N.W. 2d 510, 516 (Mich. App. 1995) (physician was sophisticated user of dialysis machine).

The IFUs at issue restrict the class of surgeons who are to use the devices. They contemplate that users will be familiar with traditional surgical techniques used to treat stress urinary incontinence. The IFUs for Gynemesh PS, Prolift, and Prosima state that “[u]sers should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing” the devices. (Plaintiffs’ Motion, Ex. B at 16). The TVT IFU says “[u]sers should be familiar with surgical techniques for bladder neck suspension

and should be adequately trained in implanting the TVT system” and that it “is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence).” (ETH.MESH.00875456 (attached as Ex. B)). The TVT-O IFU says it should be used “only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in implanting the Gynecare TVT Obturator device.” (ETH.MESH. 02340829 (attached as Ex. C)).

So the important question with respect to the plaintiffs’ failure to warn claim is what “hazards” are “commonly known” to surgeons familiar with traditional non-mesh SUI surgery and mesh surgery at the time the device was implanted. Ethicon had no duty to warn of adverse events “commonly known” to those surgeons. Its duty was to warn of adverse events that were unique to the new devices, or, at the very least, unique to the use of mesh.

Evidence regarding the risks and complications that were commonly known to pelvic surgeons is also properly provided through expert testimony. Experts may testify as to the knowledge common within a profession or community. *See Flannery*, 2008 WL 77723, at *2; *Cruz-Vargas*, 348 F.3d at 277; *Articles of Device*, 426 F. Supp. at 370. The same holds true here. The proper vehicle for offering evidence as to which of the risks and complications identified by Plaintiffs were already commonly known by surgeons is through physician-experts, like Dr. Sepulveda. Indeed, this Court has previously held that physicians, like Dr. Sepulveda, may testify as to the risks of mesh surgery known by fellow surgeons.

Dr. Sepulveda’s qualifications. Dr. Sepulveda is well-qualified to render such an opinion. He has over 20 years of practice in the field and has performed over 2,000 synthetic midurethral slings since 1998. (Plaintiffs’ Motion, Ex. B at 1-2). Moreover, unlike some of the

experts Plaintiffs offer regarding the adequacy of Defendants' warnings, Dr. Sepulveda has actually used the devices, IFUs, and brochures at issue in his practice.³ (*Id.* at 2).

In addition, as an instructor for Ethicon, he has conducted surgical anatomy laboratories with the use of models and cadavers, consensus conferences among experienced users, surgical demonstrations in the operating room, and didactic lectures. (*Id.* at 18; Plaintiffs' Motion, Ex. C at 22; 10/22/08 Email (ETH.MESH.07383398-401)). In this professional education role, Dr. Sepulveda covered and taught to fellow surgeons the IFUs at issue. (Sepulveda 3/30/16 Dep. Tr. (attached as Ex. D) 275:24 – 276:16). As he testified at his deposition, the IFU was taught at “every single lab” and that “as a preceptor or as teacher, you need to know that IFU by – by steps and know not only what it says, but what it really says in terms of mechanics.” (*Id.*). Dr. Sepulveda further noted in his reports that “[a]ll these activities offer the opportunity to address the complications and details of the surgery along with the interpretation of the IFU.” (Plaintiffs' Motion, Ex. B at 18; Plaintiffs' Motion, Ex. C at 22).

His opinion also rests on literature and professional association statements. Yet Dr. Sepulveda's opinion is not based solely on his lengthy and distinguished clinical experience. Instead, Dr. Sepulveda also relies on an in-depth review of the medical literature, as outlined in his reports. These include numerous studies comparing mesh to non-mesh surgery.⁴ He has also

³ Plaintiffs incorrectly suggest that Dr. Sepulveda is not familiar with the IFU for TVT because he testified that the last time he reviewed it was six years ago. (Plaintiffs' Mem. (Dkt. No. 2018) at 8). Plaintiffs fail to note that Dr. Sepulveda also testified that he is aware of the contents of the IFUs and his substantial experience with the IFUs, as detailed above, proves the point. (Sepulveda 3/30/16 Dep. Tr. 122:8-22).

⁴ These include: Carey M, Higgs P, Goh J, Lim J, Leong A, Krause H, Cornish A. *Vaginal repair with mesh versus colporrhaphy for prolapse: a randomised controlled trial*, BJOG. 2009 Sep;116(10):1380-6; Withagen MI, Milani AL, den Boon J, Vervest HA, Vierhout ME. *Trocarguided mesh compared with conventional vaginal repair in recurrent prolapse: a randomized controlled trial*, Obstet Gynecol. 2011 Feb;117(2 Pt 1):242-50; Altman D, Väyrynen T, Engh ME, Axelsen S, Falconer C; Nordic Transvaginal Mesh Group. *Anterior colporrhaphy versus transvaginal mesh for pelvic-organ prolapse*, N Engl J Med. 2011 May 12;364(19):1826-36. doi: 10.1056/NEJMoa1009521. Erratum in: N Engl J Med. 2013 Jan 24; 368(4):394; Sokol AI, Iglesia CB, Kudish BI, Gutman RE, Shveiky D, Bercik R, Sokol ER. *One-year objective and functional outcomes of a randomized clinical trial of vaginal mesh for prolapse*, Am J Obstet Gynecol. 2012 Jan;206(1):86.e1-9; Halaska M, Maxova K, Sottner

reviewed and relies on literature on dyspareunia and other complications common to pelvic floor surgeries.⁵ Conversely, Dr. Sepulveda has also reviewed literature on complications unique to mesh surgery, such as mesh exposure.⁶ Further, he has reviewed and relies upon literature on TVT and TVT-O, including long term studies on the devices' efficacy and complications.⁷

In his opinion, complications of traditional non-mesh surgery include voiding dysfunction, permanent retention of urine, catheterization, de novo urge incontinence, urinary tract infections, hernias, hematomas, fascial sling exposure, and granulomas. (Plaintiffs' Motion, Ex. B at 4-12; Plaintiffs' Motion, Ex. C at 5-7). The use of native tissue surgical repair for prolapse has been associated with high rates of recurrence of 30% to 50%. (Plaintiffs' Motion, Ex. B at 5). The Burch procedure has been shown to increase the risk of vaginal prolapse and also cause pain, sexual dysfunction and dyspareunia. (Plaintiffs' Motion, Ex. C at 5-6).

O, Svabik K, Mlcoch M, Kolarik D, Mala I, Krofta L, Halaska MJ, *A multicenter, randomized, prospective, controlled study comparing sacrospinous fixation and transvaginal mesh in the treatment of posthysterectomy vaginal vault prolapse*, Am J Obstet Gynecol. 2012 Oct;207(4):301.e1-7; El-Nazer MA, Gomaa IA, Ismail Madkour WA, Swidan KH, El-Etriby MA, *Anterior colporrhaphy versus repair with mesh for anterior vaginal wall prolapse: a comparative clinical study*, Arch Gynecol Obstet. 2012 Oct;286(4):965-72; Qatawneh A, Al-Kazaleh F, Saleh S, Thekrallah F, Bata M, Sumreen I, Al-Mustafa M, *Transvaginal cystocele repair using tension-free polypropylene mesh at the time of sacrospinous colpopexy for advanced uterovaginal prolapse: a prospective randomised study*, Gynecol Surg 2013; 10:79–85; Svabik K, Martan A, Masata J, El-Haddad R, Hubka P., *Comparison of vaginal mesh repair with sacrospinous vaginal colpopexy in the management of vaginal vault prolapse after hysterectomy in patients with levator ani avulsion: a randomized controlled trial*, Ultrasound Obstet Gynecol. 2014 Apr;43(4):365-71; Dos Reis Brandão da Silveira S, Haddad JM, de Jármy-Di Bella ZI, Nastri F, Kawabata MG, da Silva Carramão S, Rodrigues CA, Baracat EC, Auge AP, *Multicenter, randomized trial comparing native vaginal tissue repair and synthetic mesh repair for genital prolapse surgical treatment*, Int Urogynecol J. 2015 Mar;26(3):335-42. (See Plaintiffs' Motion, Ex. B at 8, n. 22 (citing all of the studies listed above)).

⁵These include: Francis WJ, Jeffcoate TN, *Dyspareunia following vaginal operations*, J Obstet Gynaecol Br Commonw. 1961 Feb; 68:1-10; Lowman JK, Jones LA, Woodman PJ, Hale DS, *Does the Prolift system cause dyspareunia?*, Am J Obstet Gynecol. 2008 Dec;199(6):707.e1-6. (See Plaintiffs' Motion, Ex. B at 12, ns. 25 and 26 (citing and discussing these studies)).

⁶ These include: Murphy M, Holzberg A, van Raalte H, Kohli N, Goldman HB, Lucente V; Pelvic Surgeons Network, *Time to rethink: an evidence-based response from pelvic surgeons to the FDA Safety Communication: "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse,"* Int Urogynecol J. 2012 Jan;23(1):5-9; Benbouzid S, Cornu JN, Benchikh A, Chanu T, Haab F, Delmas V, *Pelvic organ prolapse transvaginal repair by the Prolift system: evaluation of efficacy and complications after a 4.5 years follow up*, Int J Urol. 2012 Nov;19(11):1010-6. (See Plaintiffs' Motion, Ex. B at 12-13 ns. 31 and 33 (citing and discussing these studies)).

⁷ (See Plaintiffs' Motion, Ex. C at 11 ns. 27 (citing numerous, long-term studies on TVT and TVT-O)).

With mesh surgery, there are fewer wound complications than with non-mesh surgery and there are usually mesh exposures which can be conservatively managed on an outpatient basis. Studies show that anatomic superiority of Gynemesh PS and Prolift and improvements in bowel, prolapse, sexual function, urinary incontinence or urgency, voiding difficulty, and vaginal pressure/bulge. (Plaintiffs' Motion, Ex. B at 9). In addition "[t]he most recent Cochrane Review demonstrates that there are lower rates of awareness of prolapse, reoperation for prolapse, and prolapse on examination with permanent polypropylene mesh like Gynemesh PS compared to native tissue repair and there is no difference in repeat surgery for incontinence or dyspareunia versus native tissue repair." (*Id.* at 10). Studies of Prosima have produced similar results. (*Id.* at 15). Also, studies and "[s]urgical experience made clear that patients treated with TVT had less voiding dysfunction, less wound complications and less retention than the historic numbers from patients treated with pubovaginal slings, needle procedures or open retropubic procedures." (Plaintiffs' Motion, Ex. C at 13-14).

"Mesh exposure is the only unique complication with Gynemesh PS and and Prolift," but, "[i]n many cases it can be treated conservatively with estrogen or a simple office procedure to excise the exposure." (Plaintiffs' Motion, Ex. B at 12). Also studies have demonstrated a low mesh exposure rate for patients, including a study with a 54 month follow-up that reported an 85% cure rate, no reoperations for recurrence, a 5.3% mesh exposure rate (of which two cases were excised and two resolved with estrogen), and no infections. (*Id.* at 13). The complications unique to synthetic slings are erosions and extrusions. (Plaintiffs' Motion, Ex. C at 17-20). Yet studies have shown low complication rates, and, in at least one study, none of the patients having any sign of tissue reaction, erosion, or tape protrusion at their 5-year follow-up. (*Id.* at 20).

The risks of dyspareunia and hematomas are well known to surgeons performing stress incontinence repairs and are not limited to mesh surgeries. (Plaintiffs' Motion, Ex. B at 11-13). Other complications with mesh slings are of the same type as those with non-mesh surgery. (*Id.* at 8-14). Studies have shown a cure rate for mesh surgeries in the range of 85% or higher, with a much lower cure rate shown for non-mesh surgeries. (Plaintiffs' Motion, Ex. B at 8-9, 13; Plaintiffs' Motion, Ex. C at 20).

Dr. Sepulveda's Opinions. Based on these facts, it is Dr. Sepulveda's opinion that the IFUs for Gynemesh PS, Prolift, Prosima, TVT, and TVT-O specifically identify, among other things, those risks that are unique to mesh surgery. (Plaintiffs' Motion, Ex. B at 18, 39; Plaintiffs' Motion, Ex. C at 22-23). So, Dr. Sepulveda opines that "[m]esh exposure is the only unique complication" with mesh devices and that "other wound complications occur without the use of mesh." (Plaintiffs' Motion, Ex. B at 12). In addition, he opines that:

The complications such as tissue contraction, scarring, pelvic pain, and dyspareunia are well-known complications that can occur with any pelvic floor surgery, including Prolift. The complication of mesh erosion or exposure is a wound complication like those seen with non-synthetic mesh repair and is not caused by a defect in the mesh. These are well-known complications that surgeons learn in medical school, residency, fellowship, through continued medical education, peer-reviewed literature, discussions with colleagues, and the FDA Public Health Notifications.

(*Id.* at 18).

This is testimony that directly addresses the appropriate legal standard, which cannot be applied without evidence of what is "commonly known" to the class of foreseeable users about the risks of the surgery. Because it is consistent with the applicable legal test, it "fits" this case whether or not Dr. Sepulveda himself can testify what, as matter of law, need or need not be included in Ethicon's IFUs and patient brochures.

IV. Dr. Sepulveda may testify that the devices are not defective.

Plaintiffs' contention in their Wave 1 motion that Dr. Sepulveda is unqualified to say that Gynemesh PS, Prolift, Prosima, TVT, and TVT-O are not defective rests on their erroneous characterization of this as a "design" opinion. (Plaintiffs' Mem. (Dkt. No. 2018) at 8-9). Yet, as this Court held in response to Plaintiffs' same argument in Wave 1, the mere fact that Dr. Sepulveda may have used the word "design" does not transform his opinions into ones concerning the design of the TVT and TVT-O. *See In re Ethicon, Inc.*, 2016 WL 4536872, at *3. Thus, the Court concluded that "Dr. Sepulveda-Toro has not expressed any opinions about the process of designing a product" and denied Plaintiffs' motion as moot. *Id.*

This same ruling should apply here. Plaintiffs' do not identify any additional opinions, testimony, or case law in support of their arguments. Instead, as noted above, they simply adopt their same briefing from Wave 1. As the record here is unchanged, Plaintiffs' motion to exclude Dr. Sepulveda's "design" opinions should once again summarily be denied as moot.

V. Dr. Sepulveda may testify as to the value (or lack thereof) in explants and offer critiques of Plaintiffs' experts' pathological opinions.

Plaintiffs wrongly seek to exclude certain testimony by Dr. Sepulveda because he is not a pathologist. In response to these exact same arguments in Wave 1, the Court denied Plaintiffs' motion after finding that Dr. Sepulveda has "extensive experience studying the relevant part of the body, both through surgery and through the dissection of hundreds of cadaver specimens" and that "[h]e has also written a manual on dissection and how to make the best specimens." *See In re Ethicon, Inc.*, 2016 WL 4536872, at *4. The Court also held that Plaintiffs failed to provide sufficient specificity of the critiques of Plaintiffs' pathologists by Dr. Sepulveda that they contend should be excluded. *Id.*

Plaintiffs' arguments should again suffer the same fate. Although Dr. Sepulveda is not a pathologist, he has a wealth of relevant experience that qualifies him to offer the opinions at

issue. The record here is the same as Plaintiffs have provided no new facts or arguments that might dictate a different result. Plaintiffs' request to exclude Dr. Sepulveda's testimony should therefore be rejected.

VI. Dr. Sepulveda may testify as to the general number of studies done on the devices and offer opinions on degradation.

Plaintiffs' overwrought characterization of Dr. Sepulveda's reference to the general number of studies performed on the devices at issue as "outlandish" and "conjecture" do not support any limits on his testimony. (Plaintiffs' Mem. (Dkt. No. 2018) at 10-11). In response to these same arguments in Wave 1, the Court reserved ruling "until the evidence may be evaluated firsthand at trial." *See In re Ethicon, Inc.*, 2016 WL 4536872, at *4. Ethicon asks that the Court adopt the same course here or simply reject Plaintiffs' arguments outright.

As detailed above, Dr. Sepulveda cites to and discusses for pages of his reports numerous studies of Gynemesh PS, Prolift, Prosima, TVT, and TVT-O. *See supra*. His list of resources relied upon contains even more. (List of Materials Relied Upon For Gynemesh PS, Prolift, Prosima, TVT, and TVO-O Reports (attached as Ex. E)). Dr. Sepulveda has performed an exhaustive review of the relevant scientific literature and not just for his work in this case, but also in his daily practice. (Plaintiffs' Motion, Exs. A at 3 (noting his regular reading of mesh research) and B at 2 (noting his regular reading of sling research)). He is more than qualified and able to offer opinions as to the general numbers of studies performed on the devices.

Plaintiffs' attempt to exclude Dr. Sepulveda's opinions regarding degradation of the devices is equally without merit. In the portion of the testimony cited by Plaintiffs, Dr. Sepulveda does not disclaim sufficient expertise to testify regarding degradation of polypropylene. Rather, his testimony is entirely consistent with his reliance on studies (or the lack thereof) performed by others regarding degradation. As Dr. Sepulveda made clear in an

earlier deposition, he has reviewed the scientific literature and not found any that support a theory of degradation. (Sepulveda 3/20/16 Dep. Tr. 176:5 – 177:14 (testifying that “there’s no evidence” of degradation and that “degradation has not been defined in a reproducible scientific way to have – to be present, or if present, to have any consequences in clinical outcomes”) and 282:14 – 284:21 (testifying that he had reviewed the various studies referenced by Plaintiffs’ counsel and others and that “I have not seen one yet that proves degradation with any definition that I’ve given of degradation”)). He has also reviewed the data cited by Plaintiffs’ experts and finds them without merit:

These case reports and case series of explants lack reliability and one cannot draw any causal inference from them or extrapolate their reported SEM findings to the larger population. In the referenced Clave study there were several methodologic flaws. Moreover, only a minority of the explants were reported to have surface cracking and degradation and oxidation were not shown on chemical analyses. While the purported surface changes were hypothesized to lead to adverse clinical outcomes, these hypotheses have not been confirmed.

(Plaintiffs’ Motion, Ex. B at 20)

Moreover, the Court has previously found that a urogynecologist’s extensive experience with performing mesh implant and explant surgeries can qualify him to opine on “how the product reacts inside the body.”⁸ Like the physicians in those cases, Dr. Sepulveda is a skilled urogynecologist with 24 years of experience treating pelvic floor disorders, as well as the complications resulting from the implantation of transvaginal mesh. *See supra*. He has performed thousands of stress incontinence surgeries, and has placed the vast majority of the slings through the transobturator route. His opinions are premised upon clinical observations

⁸ *Winebarger v. Bos. Sci. Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *26 (S.D. W. Va. Apr. 24, 2015); *see also Trevino*, No. 2:13-CV-01617, 2016 WL 1718836 at *4-5 (rejecting challenge to practicing urologist whose “clinical experience and review of the scientific literature adequately qualify him to opine on polypropylene, including its degradation, leaching, shrinkage, and contraction”).

from performing thousands of procedures involving mesh. (Plaintiffs' Motion, Ex. A at 1-2). Accordingly, Dr. Sepulveda is well-qualified to offer opinions regarding degradation.

VII. Dr. Sepulveda may testify that the design of TVT-O takes into account anatomical considerations.

Plaintiffs incorrectly argue that Dr. Sepulveda needed to have been involved in the design process in order to opine that the TVT-O's design accounts for anatomical considerations, in particular the hammock of the suburethra and the periurethral tissue. Although the Court did not in its Wave 1 ruling specifically address Plaintiffs' argument here, Ethicon respectfully requests that it do so now and reject Plaintiffs' request to exclude this testimony.

As detailed above, Dr. Sepulveda has performed numerous dissections and even written a manual instructing others on how to perform dissections and make use of specimens. Indeed, the Court acknowledged in this experience when holding that Dr. Sepulveda is qualified to testify as to the value of explanted materials. *See In re Ethicon, Inc.*, 2016 WL 4536872, at *4. When instructing in Ethicon's cadaver labs, Dr. Sepulveda necessarily broke-down for fellow surgeons the anatomical effects of mesh devices. Indeed, he notes in his TVT and TVT-O report that he has "dissected the [urethral] area in cadavers extensively and been able to confirm the support to the urethra in this area." (Plaintiffs' Motion, Ex. C at 8; *see also* 8 n. 15-17 (anatomical studies), 20 (anatomic considerations of the TVT-Os design) and 20 n. 66 (*citing* relevant literature)). Accordingly, Dr. Sepulveda need not have been present at the design of TVT-O to opine as to whether it is consistent with the anatomical considerations he has witnessed first hand in countless dissections. Plaintiffs' request to exclude such testimony should be denied.

VIII. Dr. Sepulveda may testify that mechanical cut tape is not defective.

Plaintiffs misconstrue the scientific literature and evidence in trying to exclude Dr. Sepulveda's testimony that mechanical cut tape is not defective. In response to these same

arguments in Wave 1, the Court held that Plaintiffs’ “objections [are] insufficient to credibly call into question the reliability” of Dr. Sepulveda’s opinion and therefore denied Plaintiff’s motion. *See In re Ethicon, Inc.*, 2016 WL 4536872, at *4. Plaintiffs’ effort to exclude this same testimony should once again be rejected. Plaintiffs do not identify any new facts or arguments that would alter the record before the Court. Instead, the record remains the same and Plaintiffs’ motion should again be denied.⁹

CONCLUSION

Dr. Sepulveda’s distinguished and lengthy career, together with his extensive review of the scientific literature and many interactions with fellow colleagues, qualifies him to offer the opinions at issue. His methodology of relying on these experiences and interactions and his review of the literature in reaching his conclusion is sound. The Court should enter an order denying Plaintiffs’ motion to limit the opinions and testimony of Dr. Sepulveda.

ETHICON, INC. AND
JOHNSON & JOHNSON

/s/ David B. Thomas

David B. Thomas (W. Va. Bar No. 3731)
Thomas Combs & Spann, PLLC
300 Summers Street, Suite 1380
P.O. Box 3824
Charleston, WV 25338-3824
(304) 414-1800

⁹ Also, Plaintiffs’ request to exclude use of the term “gold standard” remains moot, as this Court held in its Wave 1 ruling. *See Ethicon*, 2016 WL 4536872, at *4. Dr. Sepulveda testified that he prefers “clinical standard” rather than “gold standard,” which he views as a marketing term. (Ex. D at 74:15 – 75:6). Finally, Plaintiffs misread Dr. Sepulveda’s report in claiming he opines that the Section 510(k) process demonstrated TVT’s tolerability and safety. He instead cites to a 2001 study by Folconer, Soderberg, Blomgren, and Ulmsten in support of his opinion that “tolerability and safety has been proven by the predicate device and graft, in this case the TVT Prolene polypropylene mesh tape.” (Plaintiffs’ Motion, Ex. C at 24 n. 72). Dr. Sepulveda does not intend to opine on the Section 510(k) process in a manner inconsistent with this Court’s prior rulings

/s/ Christy D. Jones

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Ridgeland, MS 39158-6010
(601) 985-4523

*Attorneys for Defendants,
Ethicon, Inc. and Johnson & Johnson*

CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on August 28, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones

Christy D. Jones

Exhibit A

From: Meek, Andrew [ETHUS] <ameek@its.jnj.com>
Sent: Thu, 23 Oct 2008 15:33:15 GMT
To: Caro-Rosado, Lissette [ETHUS] <LCaro@its.jnj.com>
Subject: FW: Information Regarding FDA Notification of Use of Mesh in Pelvic Surgery

-----Original Message-----

From: Jaime Sepulveda [mailto:sepu@aol.com]
Sent: Wednesday, October 22, 2008 11:33 PM
To: Granahan, Michele [ETHUS Non-J&J]
Cc: Zipfel, Robert [ETHUS]; Zipfel, Robert [ETHUS]; Meek, Andrew [ETHUS]
Subject: Re: Information Regarding FDA Notification of Use of Mesh in Pelvic Surgery

Dr. Robinson and Dr. Kirkemo,

At the light of the FDA warning on mesh complications I find appropriate to make you aware of the activities devoted to the subject of complications in advanced pelvic surgery using mesh at the preceptorships at South Miami Hospital. Since 2007 the subject of complications associated to the use of Prolift, TVTO, TVT and TVT Secur have been addressed on every professional education activity including every cadaver lab and live surgery preceptorship I have lead.

The following methods and resources have been used:

A copy of the updated monograph with detailed information about complications associated to the use of Prolift has been provided to every physician attending the preceptorships at South Miami Hospital. The monograph is discussed throughout the full day of training. The IFU for Prolift and TVT Secur is included.

A full hour didactic presentation discussing the diagnosis, management and prevention of complications is dedicated separately from the didactics in Prolift technique and indications. The content of the presentation includes

imaging of mesh, removal , complications associated to placement - dissection and best strategies for prevention. During the presentation and afterwards the attendees are prompted to share their experience related to complications and the counseling of patients. It is interactive and peer driven.

The mechanism for reporting complications to the FDA and to EWH&U is discussed. If time allows the attendees get a view of the facilities used to monitor our outcomes through the American College of Surgeons National Surgical Quality Improvement Program. The ACS NSQIP uses a nationally developed methodology to track complications through a blinded review. I believe we are the first institution to use it specifically for the use of mesh in prolapse surgery.

A list of recommended readings and peer reviewed publications is presented at the conclusion of the didactic program on complications. I also include a slide presenting the number of total cases done here and every complication I have handled.

The patient education pamphlet is presented as an aid in the counseling of patients before surgery and its used is encouraged. The pamphlet delineates the most common complications in a clear language that the patient understands. Being in Miami all materials are available in english and spanish. I have also provided on request a copy of the postoperative instructions and postoperative orders used in our service at Miami Urogynecology Center. The postop instructions are also available in both languages.

I have had the privileged opportunity to meet again with some of the physicians trained and go over their outcomes and experiences through advanced users forums. I fly to their location and have a professional education activity consisting on a presentation and an interactive session. It is a good parameter of the relevance of the provided training and the impact on the way care is provided to their patients with prolapse and incontinence.

The use of mesh has given their life back to many women in my area. I have compiled a large number of cases with minimal complications and excellent results. Over my 18 years in a busy urogynecology practice I have learned that once a surgery changes the complications also change , not in numbers but in type. All my patients have been pleased with their meshes and have had no major problems. I am practicing at the most satisfying part of my career thanks to the use of this line of products. Lets not allow distorted perception sabotage a good surgical modality for the care of our patients. Lets continue to lead through evidence based education.

Jaime

L. Sepulveda, MD FACS FACOG

On 10/22/08 3:32 PM, "Granahan, Michele [ETHUS Non-J&J]" <MGranah2@its.jnj.com> wrote:

FINAL - 10/21/08
Email message to Prolapse/SUI preceptors

To Advise of FDA Notification

Dear Preceptor:

On October 21, 2008, the U.S. FDA issued a Public Health Notification to healthcare professionals about complications associated with transvaginal placement of surgical mesh to treat Pelvic Organ Prolapse (POP) and Stress Urinary Incontinence (SUI). The notification was based on 1,000 reports the FDA has received, over a 3-year period, from at least 9 surgical mesh manufacturers. On average, there are about 340,000 procedures per year in the U.S. that use a mesh product to treat prolapse or stress incontinence.

The complications stated in the notification are known risks that can occur with surgical procedures of this type that use mesh. These complications are included in the labeling for our products and we have always communicated these risks in our professional education. As you know, we take the reporting of complications seriously and diligently monitor and report complications associated with the use of our devices.

If you should have any questions, please feel free to contact the ETHICON Medical Affairs department at 1-800-888-9234 extension 3800 or at ETH_MEDICAL_INFO@ETHUS.JNJ.co
<mailto:ETH_MEDICAL_INFO@ETHUS.JNJ.co>

Sincerely,

David Robinson, M.D.
Medical Affairs Director

Aaron Kirkemo, M.D.
Associate Medical Affairs Director

Attachment: FDA Notice

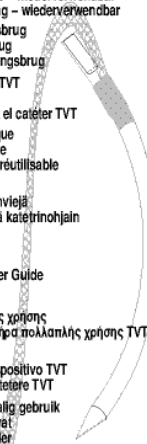
<<Document.pdf>>

Exhibit B

GYNECARE

TVT

Tension-free Vaginal Tape

- 
- (D)** TVT Implantat – Einweg
TVT Einführungsinstrument – wiederverwendbar
TVT Metall Katheter-Führung – wiederverwendbar
 - (DK)** Sterilt: TVT bånd til engangsbrug
TVT indfører til flergangsbrug
Siv TVT guidewire til flergangsbrug
 - (E)** Dispositivo de un solo uso TVT
Introduccion reutilizable TVT
Guia rigida reutilizable para el cateter TVT
 - (F)** Dispositif TVT à usage unique
Introduceur TVT réutilisable
Guide de sonde rigide TVT réutilisable
 - (FIN)** TVT neula, kertokäyttöinen
TVT toistokäyttöinen sisäänviela
TVT toistokäyttöinen jäykkä katetrinohjain
 - (GB)** TVT Single Use Device
TVT Reusable Introducer
 - (USA)** TVT Reusable Rigid Catheter Guide
 - (GR)** Συσκευή μιας χρήσης TVT
Εισαγωγός TVT πολλαπλής χρήσης
Οδηγός Δυσκολλητού Καθετήρα πολλαπλής χρήσης TVT
 - (I)** Dispositivo TVT monouso
introduttore poliuso per dispositivo TVT
Guida rigida poliuso per catetere TVT
 - (NL)** TVT instrument voor éénmalig gebruik
TVT reusable inbrenghandvat
TVT reusable cathetervoeder
 - (P)** Dispositivo TVT – Uso único
Introducion TVT – Reutilizável
Guia rigida de cateter TVT – Reutilizável
 - (S)** TVT nålar med inkontinensband för engangsbruk
TVT handtag för flergangsbruk
TVT kateterguide för flergangsbruk

Authorized Representative • Autoriseret repræsentant
Erkende vertegenwoordiger • Valtutettu edustaja
Représentant autorisé • Autorisierter Vertreter
Rappresentante autorizzato • Representante autorizado
Εξουσιοδοτημένος Αντιπρόσωπος

ETHICON® GmbH
Robert-Koch-Strasse 1
D-22851 Norderstedt
Germany

EC
Legal Manufacturer
ETHICON® SaRL
Rue de Puits Godet, CH-2000
Neuchâtel, Switzerland

CE 0123

STATUS 8/01
RMC P 15506/B

GB USA Tension-free Vaginal Tape (TVT) System –
Instructions for Use

TVT Single Use Device
TVT Reusable Introducer
TVT Reusable Rigid Catheter Guide

Please read all information carefully.
Failure to properly follow instructions may result in improper functioning of the device and lead to injury.

Important:
This package insert is designed to provide instructions for use of the Tension-free Vaginal Tape single use device, reusable introducer, reusable rigid catheter guide. It is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence). The device should be used only by physicians trained in the surgical treatment of Stress Urinary Incontinence and specifically in implanting the TVT device. These instructions are recommended for general use of the device. Variations in use may occur in specific procedures due to individual technique and patient anatomy.

DESCRIPTION (System)
TVT consists of the following:
TVT Single-Use Device, provided sterile (available separately)
TVT Reusable Introducer, provided non-sterile (available separately)
TVT Reusable Rigid Catheter Guide, provided non-sterile (available separately)

TVT DEVICE
The TVT device is a sterile single use device, consisting of one piece of undyed or blue (Phthalocyanine blue, Colour index, Number 74160) PROLENE® polypropylene mesh (tape) approximately 1/2 x 18 inches (1.1 x 45 cm), covered by a plastic sheath cut and overlapping in the middle, and held between two stainless steel needles bonded to the mesh and sheath with plastic collars.
PROLENE® polypropylene mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in PROLENE® polypropylene nonabsorbable surgical suture. The mesh is approximately 0.027 inches (0.7mm) thick. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. PROLENE® mesh is knitted by a process which interlinks each fiber junction and which provides, for elasticity in both directions. This bi-directional elastic property allows adaptation to various stresses encountered in the body.

TVT INTRODUCER
The TVT introducer is provided non-sterile and is reusable. The introducer is made of stainless steel. It consists of two parts, a handle and an inserted threaded metal shaft. The introducer is intended to facilitate the passage of the TVT device from the vagina to the abdominal skin. It is connected and fixed to the needle, via the threaded end of the shaft, prior to inserting the needle with the tape.

TVT RIGID CATHETER GUIDE
The TVT rigid catheter guide is a non-sterile reusable instrument intended to facilitate the identification of the urethra and the bladder neck during the surgical procedure. It is inserted into a Foley catheter (recommended size 18 French) positioned in the bladder via the urethra. To facilitate insertion, it can be lubricated with gel.

INDICATIONS
The TVT device is intended to be used as a pubourethral sling for treatment of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The TVT introducer and rigid catheter guide are available separately and intended to facilitate the placement of the TVT device.

INSTRUCTIONS FOR USE

The patient should be placed in the lithotomy position taking care to avoid hip flexion greater than 60°.

The procedure can be carried out under local anesthesia, but it can also be performed using regional or general anesthesia. The extent of dissection is minimal, i.e. a vaginal midline entry with a small para-urethral dissection to initially position the needle and two suprapubic skin incisions. Using forceps, grasp the vaginal wall at each side of the urethra. Using a small scalpel, make a sagittal incision about 1.5 cm long starting approximately 1.0 cm from the outer urethral meatus. This incision will cover the mid-urethral zone and will allow for subsequent passage of the sling (tape). With a small pair of blunt scissors, two small paraurethral dissections (approximately 0.5 cm) are made so that the tip of the needle can then be introduced into the paraurethral dissection. Then, two abdominal skin incisions of 0.5 – 1 cm are made, one on each side of the midline just above the symphysis not more than 4 – 5 cm apart. Incision placement and needle passage near the midline and close to the back of the pubic bone are important to avoid anatomic structures in the inguinal area and lateral pelvic sidewall.

The TVT rigid catheter guide is inserted into the channel of the Foley catheter (18 French). The handle of the guide is fixed around the catheter, proximal to its widening. The purpose of the guide is to move the bladder neck and urethra away from where the tip of the needle will pass into the retropubic space. Via use of the Foley catheter and the rigid catheter guide, the urethra and bladder are moved contralaterally to the side of the needle passage. During this maneuver, the bladder should be empty. The threaded end of the introducer is screwed into the end of one of the needles.

Using the introducer, the needle is passed paraurethally penetrating the urogenital diaphragm. Insertion and passage are controlled by using the long or index finger in the vagina under the vaginal wall on the ipsilateral side and fingertip control on the pelvic rim. The curved part of the needle should rest in the palm of the "vaginal" hand. If you are right handed this means that the left hand generally is the one to be used for needle guidance. With the other hand grip the handle of the introducer gently. Now introduce the needle tip into the retropubic space. Once again observe that this should be done by the palm of the vaginal hand and with the needle tip horizontally i.e. in the frontal plane. After passage of the urogenital diaphragm you will feel that the resistance is significantly reduced.

Immediately aim the tip of the needle towards the abdominal midline and lower the handle of the introducer thereby pressing the tip of the needle against the back of the pubic bone. Now, move the needle tip upwards to the abdominal skin incision, keeping in close contact with the pubic bone all the way.

When the needle tip has reached the abdominal incision, cystoscopy is performed to confirm bladder integrity. The bladder must be emptied after the first cystoscopy. The procedure is then repeated on the other side. The needles are then pulled upward to bring the tape (sling) loosely, i.e. without tension, under the midurethra. Cut the tape close to the needles. Now, adjust the tape so that leakage is reduced allowing a few drops of urinary leakage to occur under stress. For this, use patient feedback i.e. coughing with a full bladder (approximately 300 ml) and keep the vaginal incision temporarily closed by a gentle grip with small forceps. The plastic sheaths that surround the tape are then removed. To avoid putting tension on the tape, a blunt instrument (scissors or forceps) should be placed between the urethra and the tape during removal of the plastic sheaths. Premature removal of the sheath may make subsequent adjustments difficult. After proper adjustment of the tape, close the vaginal incision. The abdominal ends of the tape are then cut and left in subcutis. Do not suture them. Suture the skin incisions. Empty the bladder. Following this procedure, postoperative catheterization is not typically required. The patient should be encouraged to try to empty the bladder 2 – 3 hours after the operation.

CONTRAINDICATIONS

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE® polypropylene mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

WARNINGS AND PRECAUTIONS

- Do not use TVT procedure for patients who are on anti-coagulation therapy.
- Do not use TVT procedure for patients who have a urinary tract infection.
- Users should be familiar with surgical technique for bladder neck suspensions and should be adequately trained in implanting the TVT system before employing the TVT device. It is important to recognize that TVT is different from a traditional sling procedure in that the tape should be located without tension under mid-urethra.
- Acceptable surgical practice should be followed for the TVT procedure as well as for the management of contaminated or infected wounds.
- The TVT procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to local anatomy and proper passage of needles will minimise risks.
- Retropubic bleeding may occur postoperatively. Observe for any symptoms or signs before releasing the patient from hospital.
- Cystoscopy should be performed to confirm bladder integrity or recognize a bladder perforation.
- The rigid catheter guide should be gently pushed into the Foley catheter so that the catheter guide does not extend into the holes of the Foley Catheter.
- When removing the rigid catheter guide, open the handle completely so that the catheter remains properly in place.
- Do not remove the plastic sheath until the tape has been properly positioned.
- Ensure that the tape is placed with minimal tension under mid-urethra.
- PROLENE® mesh in contaminated areas should be used with the understanding that subsequent infection may require removal of the material.
- The patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
- Since no clinical experience is available with vaginal delivery following the TVT procedure, in case of pregnancy delivery via cesarian section is recommended.
- Post-operatively the patient is recommended to refrain from heavy lifting and/or exercise (i.e. cycling, jogging) for at least three to four weeks and intercourse for one month. The patient can return to other normal activity after one or two weeks.
- Should dysuria, bleeding or other problems occur, the patient is instructed to contact the surgeon immediately.
- All surgical instruments are subject to wear and damage under normal use. Before use, the instrument should be visually inspected. Defective instruments or instruments that appear to be corroded should not be used and should be discarded.
- As with other incontinence procedures, de novo detrusor instability may occur following the TVT procedure. To minimize this risk, make sure to place the tape tension-free in the mid-urethral position.
- Do not contact the PROLENE® mesh with any staples, clips or clamps as mechanical damage to the mesh may occur.
- Do not resterilize TVT device. Discard opened, unused devices.

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE® mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE® mesh is designed to minimize the risk of contamination.
- Over correction i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE® mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

INSTRUCTIONS FOR CLEANING REUSABLE INSTRUMENTS

(TVT Introducer, TVT Rigid Catheter Guide) To ensure the reliability and functionality of TVT Introducer and TVT Rigid Catheter Guide, clean the instruments before initial use and after each procedure. The following are suggested manual and automated methods for cleaning the instruments. Prior to cleaning, the TVT Introducer should be separated into its component parts (handle and threaded shaft). The Introducer is reassembled after cleaning and before sterilization.

Manual method

1. Soak the instrument components in an enzyme cleaner suitable for stainless steel instruments.
2. Wash in a surgical detergent and disinfecting solution at a temperature of 86° F to 95° F (30° C to 35° C). Remove any contamination from body fluids or tissues using a soft brush.
3. Place the instrument components in an ultrasonic bath with fresh detergent solution for approximately 10 minutes or follow the instructions below if using an automatic washing cycle.
4. Rinse thoroughly in a stream of fresh tap water followed by towel drying. The instrument components may be treated with instrument lubricant.

Automated Method:

Automatic washing cycles are suitable for stainless steel instruments.

One recommended cycle is described below:

- Rinse/Wet Cycle Cold Water – 1 minute
- Wash 176° F (80° C) – 12 minutes
- Rinse Cycle – 1 minute
- Rinse Cycle – 12 minutes
- Final Rinse – 2 minutes
- Rinse with Demineralized water 176° F (80° C) – 2 minutes
- Dry 199.4° F (93° C) – 10 minutes

STERILIZATION RECOMMENDATIONS FOR REUSABLE INSTRUMENTS

(TVT Introducer, TVT Rigid Catheter Guide)

The TVT Introducer, TVT Rigid Catheter Guide are supplied non-sterile. To sterilize, steam autoclave prior to each use. Steam autoclave at a temperature of 270° F to 284° F (132° C to 140° C) for a minimum of 4 minutes (pre-vacuum). It is the responsibility of the end user to assure sterility of the product when using sterilization process recommended, since bioburden and sterilization equipment will vary.

INSTRUMENT MAINTENANCE

- TVT Introducer

Before each use, inspect the threaded parts of the inner shaft.

- TVT Rigid Catheter Guide

Before each use, inspect the instrument. Check to ensure that the long end which traverses the catheter channel has no sharp edges or burrs.

HOW SUPPLIED

The TVT device is provided sterile (ethylene oxide) for single use. Do not re-sterilize. Do not use if package is opened or damaged. Discard opened, unused devices. The reusable TVT introducer, TVT rigid catheter guide are supplied separately, and are non-sterile. These accessories are to be cleaned and sterilized prior to each use as described above.

STORAGE

Recommended storage conditions for the TVT single use device are below 25° C, away from moisture and direct heat. Do not use after expiry date.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

EC

Legal Manufacturer:

ETHICON® SARL
Rue du Puits Godet 20
CH-2000 Neuchâtel
Switzerland

Distributor (Europe):

ETHICON® Ltd.
Bankhead Avenue
Edinburgh, EH11 4 HE
United Kingdom

Distributor (USA):

Gynccare
a division of ETHICON®, Inc.
a Johnson & Johnson Company
Somerville, NJ
08876-0151

Exhibit C

GYNECARE TVT*

Obturator System

Tension-free Support for Incontinence

GYNECARE TVT* *obturatorstysteem*
Spanningsvrij steunbandje tegen incontinentie

GYNECARE TVT* *obturatorssystem*
Spændingsfri støtte til inkontinens

GYNECARE TVT* *-obturaattorijärjestelmä*
Jännityksetön tuki inkontinenssin hoitoon

Système obturateur GYNECARE TVT*
Dispositif sans tension contre les incontinences

GYNECARE TVT* *Obturator System*
Spannungsfreie Unterstützung bei Inkontinenz

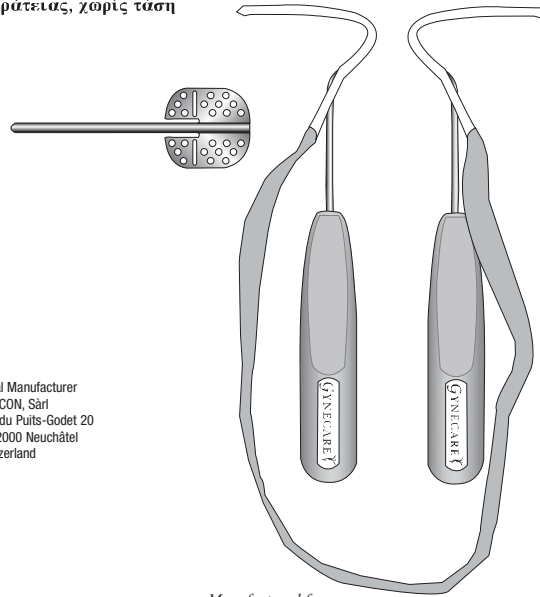
Sistema otturatorio GYNECARE TVT*
Dispositivo tension-free per l'incontinenza

Sistema obturador GYNECARE TVT*
Apoio sem tensão para incontinência

Sistema obturador GYNECARE TVT*
Protector sin tensión para la incontinencia

GYNECARE TVT* *obturatoribandsystem*
Tensionsfritt stöd för behandling av inkontinens

Σύστημα επιπωματικού GYNECARE TVT*
Σύστημα υποστήριξης για την αντιμετώπιση της
ακράτειας, χωρίς τάση



EC
Legal Manufacturer
ETHICON, Sàrl
Rue du Puits-Godet 20
CH-2000 Neuchâtel
Switzerland

Manufactured for:

GYNECARE
WORLDWIDE
A division of **ETHICON, INC.**
a Johnson & Johnson company
Somerville, New Jersey 08876-0151

Made in Switzerland
©ETHICON, INC. 2003 *Trademark

RMC P18070/A

ENGLISH

**GYNECARE TVT* *Obturator System*
Tension-free Support for Incontinence**

**GYNECARE TVT *Obturator Device*,
Sterile Single Use**

**GYNECARE TVT *Obturator Helical Passers*,
Sterile Single Use**

**GYNECARE TVT *Obturator Atraumatic Winged Guide*,
Sterile Single Use**

Please read all information carefully.

Failure to properly follow instructions may result in improper functioning of the device and may lead to injury.

Important:

This package insert is designed to provide instructions for use of the GYNECARE TVT* *Obturator System*, including the GYNECARE TVT *Obturator device*, Helical Passers and Atraumatic Winged Guide. It is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence). The device should be used only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in implanting the GYNECARE TVT *Obturator device*. These instructions are intended for general use of the device. Variations in use may occur in specific procedures due to individual technique and patient anatomy.

DESCRIPTION

The GYNECARE TVT *Obturator System* is a sterile, single patient use procedure kit consisting of:

GYNECARE TVT *Obturator device*

The GYNECARE TVT *Obturator device* is a sterile, single patient use device, consisting of one piece of undyed or blue (Phthalocyanine blue, Color index Number 74160) PROLENE* polypropylene mesh (tape) approximately 1/2 x 18 inches (1.1 x 45 cm) covered by a plastic sheath overlapping in the middle. Plastic tube receptacles are attached at each end. PROLENE polypropylene mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in PROLENE polypropylene non-absorbable surgical suture. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. PROLENE mesh is knitted by a process that interlinks each fiber junction and that providing elasticity in both directions. This bi-directional elastic property allows adaptation to various stresses encountered in the body.

GYNECARE TVT *Helical Passers*

The GYNECARE TVT *Helical Passers* are two stainless steel, curved wire passers with plastic handles that are designed to deliver the GYNECARE TVT *Obturator device*. Helical Passers are provided as left and right units, pre-assembled to the GYNECARE TVT *Obturator device*. The Helical Passer MUST not be bent or deformed in any way.

GYNECARE TVT *Atraumatic Winged Guide*

The GYNECARE TVT *Atraumatic Winged Guide* is a stainless steel accessory instrument, which facilitates the passage of the GYNECARE TVT *Helical Passers* through the dissection tract.

INDICATIONS

The GYNECARE TVT *Obturator device* is intended to be used in women as a sub-urethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

INSTRUCTIONS FOR USE

(Note: hand positions shown in illustrations may vary)

1. Place the patient in the dorsal lithotomy position with the hips hyperflexed over the abdomen. The buttocks should be positioned flush with the edge of the table.
2. The procedure can be carried out under local, regional or general anesthesia.
3. Optionally, the labia may be sutured laterally to provide exposure.
4. Insert a urethral catheter into the bladder and empty the bladder.
5. Mark the exit points of the plastic tubes by tracing a horizontal line at the level of the urethral meatus, and a second line parallel and 2 cm above the first line. Locate the exit points on this line, 2 cm lateral to the folds of the thigh (the skin may be flattened by stretching). Mark the exit points, alternatively a 5–10 mm incision may be made at each exit point or at a later stage of the procedure. (See Figure 1)

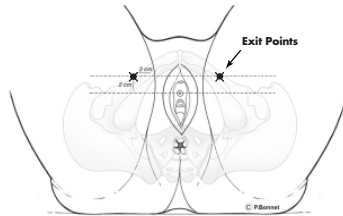


FIG. 1

6. Using Allis clamps for traction, make a 1 cm midline incision in the vaginal mucosa starting 1 cm proximal to the urethral meatus.

(Note: It is suggested that the device insertion be completed on one side before beginning dissection of the second side.)

Using a "push-spread technique", begin blunt dissection preferably using pointed, curved scissors. The path of the lateral dissection should be oriented at a 45° angle from the midline, with the scissors oriented either on the horizontal plane or with the tips pointed slightly upward (See Figure 2). Continue dissection toward the "junction" between the body of the pubic bone and the inferior pubic ramus. (See Figure 2)

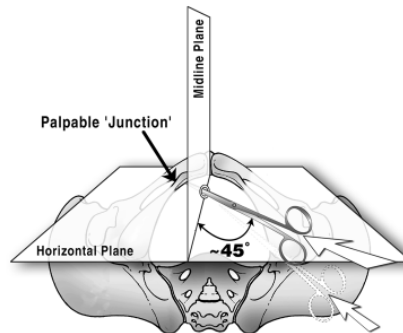


FIG. 2

When the "junction" between the body of the pubic bone and the inferior pubic ramus is reached, perforate the obturator membrane. A loss of resistance can be felt when the membrane is perforated. The channel should be approximately 5–7 mm in diameter and no deeper than 5 cm. Dissection beyond 5 cm may allow unintended entry into the Space of Retzius. If the bone is not reached after dissecting 5 cm, re-evaluate that the angle of dissection is correct.

7. Remove the GYNECARE TVT Winged Guide from the package. (See Figure 3)

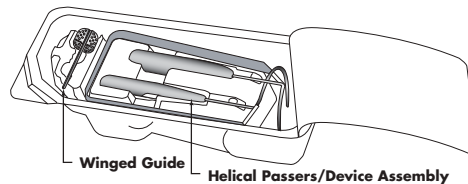


FIG. 3

8. Insert the GYNECARE TVT Winged Guide into the dissected tract until it passes the inferior pubic ramus and enters the opening previously made in the obturator membrane. Loss of resistance can be felt as the Winged Guide passes through the obturator membrane.

If difficulty is encountered during insertion of the guide, reconfirm the direction of the tract with the scissors.

(Note: The open side of the guide must be facing the surgeon. The bendable tab can be bent to increase the length of the guide if needed, See Figure 5.)

9. Remove the GYNECARE TVT Helical Passers/Device Assembly and the GYNECARE TVT Obturator device assembly from the sterile pack (See Figure 3 for components).

(Note: To ensure correct orientation of the Helical Passers and tape, verify that the GYNECARE logo and thumb indent on the plastic handle are facing the surgeon, and that the points are on the outside facing the surgeon. The Helical Passer in the surgeon's left hand must be used on the patient's right side; See Figure 4.)

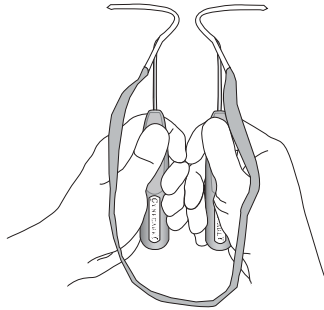


FIG. 4

10. Place one of the Helical Passers on the sterile drape or other suitable sterile location until needed. Assume that the tape is not twisted.
11. Insert the correct GYNECARE TVT Helical Passer into the dissected tract following the channel of the GYNECARE TVT Winged Guide. Push the device inward, traversing, and slightly passing the obturator membrane. Make sure the device handle is oriented so the straight tip of the Helical Passer is aligned with the channel in the GYNECARE TVT Winged Guide and remains in that orientation until the tip traverses the obturator membrane. (See Figure 5)

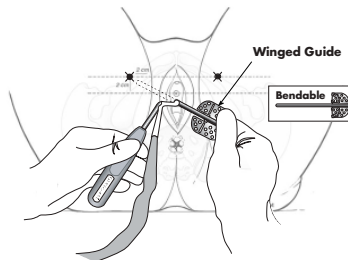


FIG. 5

12. Once in this position, remove the GYNECARE TVT Winged Guide and keep sterile for later use on the same patient.

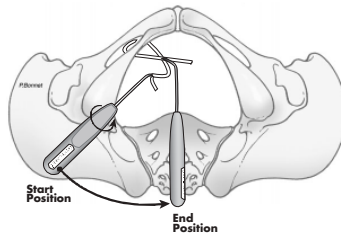


FIG. 6

13. Once the GYNECARE TVT Winged Guide has been removed, rotate the handle of the Helical Passer simultaneously as you move the handle towards the midline. (See Figure 6) **(Note: Never allow the handle to be orientated in a horizontal position.)**

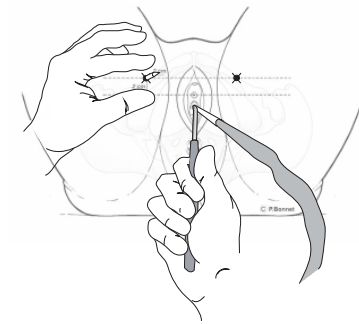


FIG. 7

14. The point of the Helical Passer should exit near the previously determined exit points (See Figure 7). However, slight skin manipulation may be required. If the skin incision has not been previously made, make it at the point where the tip of the helical passer tents the skin. When the tip of the plastic tube appears at the skin opening, grasp it with a clamp and, while stabilizing the tube near the urethra remove the Helical Passer by a reverse rotation of the handle. (See Figure 8)

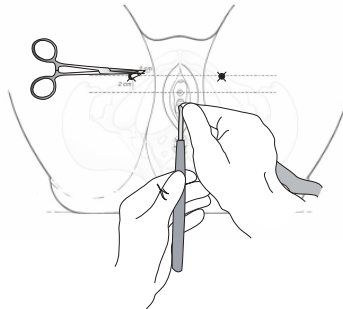


FIG. 8

15. Pull the plastic tube completely through the skin until the tape appears. (See Figure 9)

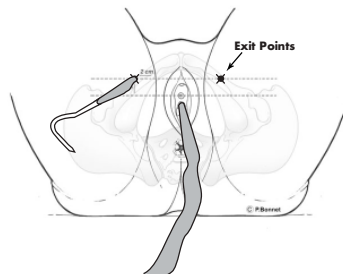


FIG. 9

16. Repeat the technique on the patient's other side ensuring that the tape lies flat under the urethra. (See Figure 10)

(Note: If a twist in the tape is discovered, ensure that the twist is not positioned under the urethra after the excess tape is pulled through.)

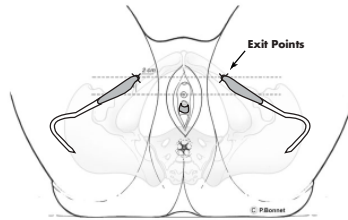


FIG. 10

17. When both plastic tubes have been extracted through the skin incisions, cut the plastic tubes from the tape and plastic sheaths. Position the tape loosely e.g. without tension, and flat under the mid-urethra. At this stage a cough test can be performed. This allows adjustment of the tape so that only a few drops of urine are lost during the cough. (See Figure 11)

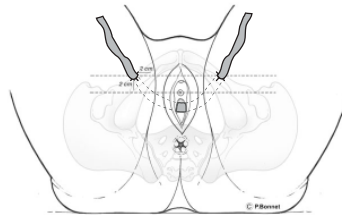


FIG. 11

When the tape is in position, remove the plastic sheath that covers the tapes. To avoid positioning the tape with tension, place a blunt instrument (e.g., scissors or forceps) between the urethra and the tape during removal of the plastic sheaths.

(Note: Premature removal of the sheath may make subsequent adjustments difficult.)

18. Following tape adjustment close the vaginal incision. Cut the tape ends at the exit points just below the skin of the inner thigh. Close the skin incisions with suture or surgical skin adhesive.
19. Cystoscopy can be performed at the discretion of the surgeon. If cystoscopy was performed following the first passage, make sure the bladder is emptied prior to initiating passage of the second side. Post-operative indwelling catheterization is not typically required. The patient should be encouraged to try to empty the bladder 2–3 hours after the operation.

CONTRAINDICATIONS

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE polypropylene mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

WARNINGS AND PRECAUTIONS

- Do not use GYNECARE TVT *Obturator* procedure for patients who are on anti-coagulation therapy.
- Do not use GYNECARE TVT *Obturator* procedure for patients who have a urinary tract infection.
- Users should be familiar with surgical technique for urethral suspensions and should be adequately trained in the GYNECARE TVT *Obturator* procedure before employing the GYNECARE TVT *Obturator* device.
- Acceptable surgical practice should be followed for the GYNECARE TVT *Obturator* procedure as well as for the management of contaminated or infected wounds.
- The GYNECARE TVT *Obturator* procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to patient anatomy and correct passage of the device will minimize risks.
- Bleeding may occur post-operatively. Observe for any symptoms or signs before releasing the patient from hospital.
- Although bladder injury is unlikely to occur with this technique, cystoscopy may be performed at the discretion of the surgeon.
- Do not remove the plastic sheaths until the tape has been properly positioned.
- Ensure that the tape is placed with no tension under the mid-urethra.
- Do not perform this procedure if you think the surgical site may be infected or contaminated.

- Since no clinical information is available about pregnancy following sub-urethral sling procedure with the GYNECARE TVT *Obturator* System, the patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
- Since no clinical information is available about vaginal delivery following a sub-urethral sling procedure with the GYNECARE TVT *Obturator* System, in case of pregnancy delivery via cesarean section should be considered.
- Post-operatively, the patient should be advised to refrain from heavy lifting and/or exercise (e.g., cycling, jogging) for at least three to four weeks and intercourse for one month. The patient can usually return to other normal activity after one or two weeks.
- The patient should be instructed to contact the surgeon immediately if dysuria, bleeding or other problems occur.
- Transient leg pain lasting 24–48 hours may occur and can usually be managed with mild analgesics.
- As with other incontinence procedures, de novo detrusor instability may occur following a sub-urethral sling procedure utilizing the GYNECARE TVT *Obturator* System. To minimize this risk, make sure to place the tape as described above.
- Do not contact the PROLENE mesh with any staples, clips or clamps as mechanical damage to the mesh may occur.
- Do not resterilize GYNECARE TVT *Obturator* device or its components. Discard opened, unused devices.
- Prophylactic antibiotics can be administered according to the surgeon's usual practice.

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation or inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheaths initially covering the PROLENE mesh are designed to minimize the risk of contamination.
- Over correction, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue, that can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

HOW SUPPLIED

The GYNECARE TVT *Obturator* System is provided sterile (ethylene oxide) for single use. Do not resterilize. Do not use if package is opened or damaged. Discard opened, unused devices.

STORAGE

Recommended storage conditions for the GYNECARE TVT *Obturator* System single use device are below 25°C, away from moisture and direct heat. Do not use after expiry date.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

*Trademark

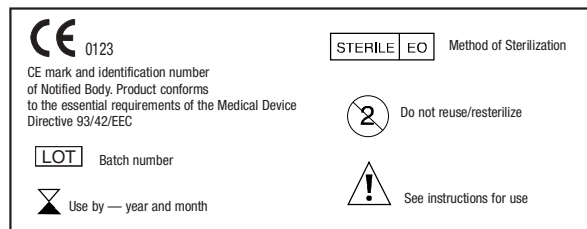


Exhibit D

Jaime Sepulveda, M.D.

Page 1

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC.,	Master File No.
PELVIC REPAIR SYSTEM PRODUCTS	2:12-MD-02327
LIABILITY LITIGATION,	MDL No. 2327
/	JOSEPH R. GOODWIN
THIS DOCUMENT RELATES TO	U.S. DISTRICT JUDGE

PLAINTIFFS:

Joplin, Deborah Lynn	2:12-cv-00787
Wheeler, Pamela Gray	2:12-cv-00455
Collins, Fran	2:12-cv-00931
Frye, Jackie	2:12-cv-01004
Bennett, Dina Sanders	2:12-cv-00497
Miracle, Charlene	2:12-cv-00510
Adams, Joan	2:12-cv-001203
Grabowski, Louise	2:12-cv-00683
Vignos-Ware, Barbara	2:12-cv-00761
Harter, Beth	12-cv-00737
Scholl, Sheri	12-cv-00738
Stubblefield, Margaret	12-cv-00842
Warmack, Roberta	12-cv-01150
Smith, Carrie	2:12-cv-00258
Thomas (Wyatt), Kimberly	2:12-cv-00499
Georgilakis, Teresa	2:12-cv-00829
Cone, Mary	2:12-cv-00261
Destefano-Raston, Dina	2:12-cv-01299
Hooper, Nancy	2:12-cv-00493
Lee, Alfreda	2:12-cv-01013
Reyes, Jennifer	2:12-cv-00939
Fisk, Paula	2:12-cv-00848
Sikes, Jennifer	2:12-cv-00501
Swint, Isabel	2:12-cv-00786
Teasley, Krystal	2:12-cv-00500
Thaman(Reeves), Susan	2:12-cv-00279
Warlick, Cathy	2:12-cv-00276
Sheperd, Donna	2:12-cv-00967

DEPOSITION OF JAIME SEPULVEDA, M.D.

Wednesday, March 30, 2016
8:12 a.m. - 4:33 p.m.
200 South Biscayne Blvd.
Miami Beach, Florida

Jaime Sepulveda, M.D.

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<p>1 APPEARANCES:</p> <p>2 On behalf of Plaintiffs:</p> <p>3 EDWARDS & DE LA CERDA</p> <p>4 3031 Allen Street, Suite 100</p> <p>5 Dallas, Texas 75204</p> <p>6 888.795.3352</p> <p>7 BY: PETER DE LA CERDA, ESQUIRE</p> <p>8 peter@edwardsdelacerda.com</p> <p>9</p> <p>10 MOSTYN LAW</p> <p>11 6280 Delaware Street</p> <p>12 Beaumont, Texas 77706</p> <p>13 800.400.4000</p> <p>14 BY: MARK C. SPARKS, ESQUIRE</p> <p>15 mark@mostynlaw.com</p> <p>16</p> <p>17 On behalf of Defendant:</p> <p>18</p> <p>19 BUTLER SNOW, LLP</p> <p>20 500 Office Center Drive</p> <p>21 Suite 400</p> <p>22 Fort Washington, Pennsylvania 19034</p> <p>23 267.513.1884</p> <p>24 BY: NILS B. SNELL, ESQUIRE</p> <p>burt.snell@butlersnow.com</p>	<p>1 Exhibit 9 Thumb Drive with Materials 49</p> <p>2 Relating to Prolift</p> <p>3</p> <p>4 Exhibit 10 Thumb Drive with Materials 50</p> <p>5 Relating to RVT-S</p> <p>6 Exhibit 11 Medical Literature 51</p> <p>7 Exhibit 12 Article: Randomized controlled 52</p> <p>8 trial comparing TVT-O and TVT-S</p> <p>9 for the treatment of stress</p> <p>10 urinary incontinence: 2-year</p> <p>11 results</p> <p>12 Exhibit 13 Curriculum Vitae 53</p> <p>13 Exhibit 14 Reliance List 54</p> <p>14 Exhibit 15 General Expert Opinion Report 55</p> <p>15 on Gynemesh PS, Prolift and</p> <p>16 Prosima</p> <p>17 Exhibit 16 General Expert Opinion Report 55</p> <p>18 on TVT and TVT-O</p> <p>19</p> <p>20 Exhibit 17 Invoices 60</p> <p>21</p> <p>22 Exhibit 18 Thumb Drive with Presentation 71</p> <p>23 Material</p> <p>24</p>
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<p>1</p> <p>2 INDEX</p> <p>3 Examination Page</p> <p>4 Direct By Mr. De La Cerda 5</p> <p>5 Cross By Mr. Snell 269</p> <p>6</p> <p>7 Certificate of Oath 302</p> <p>8 Certificate of Reporter 303</p> <p>9</p> <p>10 EXHIBITS</p> <p>11 No. Page</p> <p>12 Exhibit 1 Gynecare Prolift and Gynecare 43</p> <p>13 Gynemesh PS Preceptor</p> <p>14 Presentation Kit</p> <p>15 Exhibit 2 Surgeon's Resource Monograph 43</p> <p>16 Exhibit 3 Medical Literature 44</p> <p>17 Exhibit 4 Book: Biomechanics: Mechanical 46</p> <p>18 Properties of Living Tissues,</p> <p>19 Chapter 7</p> <p>20 Exhibit 5 Book: Introductory 46</p> <p>21 Biomechanics From Cells to</p> <p>22 Organisms, Chapter 9</p> <p>23 Exhibit 6 Book: Introductory 47</p> <p>24 Biomechanics From Cells to</p> <p>Organisms, Chapter 12</p> <p>Exhibit 7 Thumb Drive with Materials 49</p> <p>Related to TVT and TVT-O</p> <p>Exhibit 8 Thumb Drive with Materials 49</p> <p>Relating to TVT-S</p>	<p>1 PROCEEDINGS</p> <p>2 - - -</p> <p>3 Thereupon:</p> <p>4 JAIME SEPULVEDA, M.D.,</p> <p>5 having been first duly sworn, was examined and</p> <p>6 testified as follows:</p> <p>7 THE WITNESS: I do.</p> <p>8 DIRECT EXAMINATION</p> <p>9 BY MR. DE LA CERDA:</p> <p>10 Q. Okay. Doctor, could you please state your</p> <p>11 full name for the record?</p> <p>12 A. Jaime L. Sepulveda.</p> <p>13 Q. You're a urogynecologist hired by Johnson &</p> <p>14 Johnson and Ethicon, Inc. to provide opinions in</p> <p>15 support of TVT, TVT-O, Gynemesh, Prolift and Prosima;</p> <p>16 correct?</p> <p>17 MR. SNELL: Form.</p> <p>18 A. I have -- I have been subpoenaed to provide</p> <p>19 expert testimony about these products.</p> <p>20 Q. (By Mr. De La Cerda) My name is Peter</p> <p>21 de al Cerda, I'm one of the attorneys who represents</p> <p>22 the plaintiffs' group.</p> <p>23 Do you understand who I am and who I</p> <p>24 represent?</p>

2 (Pages 2 to 5)

Jaime Sepulveda, M.D.

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<p>1 A. Yes, I do.</p> <p>2 Q. A couple of deposition rules. As we begin,</p> <p>3 first of all, we want to try to let each other finish,</p> <p>4 so allow my question to get out fully before you begin</p> <p>5 your answer and then I'll allow your answer to get out</p> <p>6 fully before I begin my next question. Is that fair?</p> <p>7 A. Yes.</p> <p>8 Q. And also when you're responding to</p> <p>9 questions, please do so verbally as opposed to an</p> <p>10 "uh-huh" or "uh-uh" or a head nod so it is clear on</p> <p>11 the record. Okay?</p> <p>12 A. Yes.</p> <p>13 Q. Also, if you don't understand my question,</p> <p>14 please ask me to repeat or rephrase it, otherwise,</p> <p>15 I'll assume that you understood my question. Is that</p> <p>16 fair?</p> <p>17 A. Yes.</p> <p>18 Q. And, of course, if you need a break at any</p> <p>19 time, please let me know and we'll take a break. The</p> <p>20 only thing is if there's a question pending, I ask the</p> <p>21 question be responded to before we take the break.</p> <p>22 Okay?</p> <p>23 A. I -- I understand.</p> <p>24 Q. All right. This is not the first deposition</p>	<p>1 you were the treater, what type of case was that? I</p> <p>2 know it's medical malpractice, but what was the</p> <p>3 subject of that case?</p> <p>4 A. That -- that was in 1994, a pelvic mass,</p> <p>5 specifically a sacral mass.</p> <p>6 Q. Okay. And then how about the one where you</p> <p>7 acted as the expert for the defense?</p> <p>8 A. It was a case of urinary incontinence after</p> <p>9 a vaginal delivery.</p> <p>10 Q. And do you recall approximately when that</p> <p>11 one was?</p> <p>12 A. That may have been three to four years ago.</p> <p>13 Q. Did either of those cases involve Butler</p> <p>14 Snow?</p> <p>15 A. No.</p> <p>16 Q. Okay. And then in the Garcia versus</p> <p>17 Ethicon, you acted as an expert on behalf of Johnson &</p> <p>18 Johnson and Ethicon; correct?</p> <p>19 A. That's correct.</p> <p>20 Q. All right. Any other depositions other than the</p> <p>21 ones you already mentioned?</p> <p>22 A. No other depositions.</p> <p>23 Q. Okay. A few questions here. I assume the</p> <p>24 answers to these are all no, but have you ever had</p>
Page 7	Page 9
<p>1 you've given; correct?</p> <p>2 A. That's correct.</p> <p>3 Q. What other depositions have you given?</p> <p>4 A. I have given depositions on Garcia versus</p> <p>5 Ethicon.</p> <p>6 Q. Okay. Anything else?</p> <p>7 A. Yes, I have given deposition in local cases</p> <p>8 against a physician.</p> <p>9 Q. Okay. So any other mesh cases where you've</p> <p>10 given a deposition other than Garcia?</p> <p>11 A. Only Garcia.</p> <p>12 Q. Okay. And then you've also given</p> <p>13 depositions, I guess, in medical malpractice cases?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. How many of those have you given?</p> <p>16 A. I have given two.</p> <p>17 Q. Two. And have you acted as a treater or as</p> <p>18 an expert in those cases?</p> <p>19 A. One was as a treater and the other one was</p> <p>20 as an expert.</p> <p>21 Q. Okay. And when you acted as the expert,</p> <p>22 were you for the plaintiff or for the defense?</p> <p>23 A. I was for the defense.</p> <p>24 Q. And generally speaking, in the case where</p>	<p>1 your privileges at a hospital revoked, suspended or</p> <p>2 limited in any way?</p> <p>3 A. No.</p> <p>4 Q. Have you ever personally been sued for</p> <p>5 medical malpractice?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. And what was the subject of that</p> <p>8 particular case?</p> <p>9 A. It -- it was, again, a chordoma,</p> <p>10 c-h-o-r-d-o-m-a, a chordoma, which is a tumor on the</p> <p>11 sacrum.</p> <p>12 Q. I see. Okay.</p> <p>13 A. And the other one was an injury to the</p> <p>14 ureter during the excision of a 20-centimeter pelvic</p> <p>15 mass.</p> <p>16 Q. Okay. So these are two separate cases;</p> <p>17 correct?</p> <p>18 A. Yes.</p> <p>19 Q. In the first case that involved the</p> <p>20 chordoma, so you were the defendant in that case?</p> <p>21 A. Yes.</p> <p>22 Q. And was this the one from 1994?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. So you actually gave a deposition in</p>

3 (Pages 6 to 9)

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<p>1 that case; right? Is that right?</p> <p>2 A. Yes.</p> <p>3 Q. And in the second case, the injury to ureter</p> <p>4 with the pelvic mass, did you end up not giving a</p> <p>5 deposition in that case?</p> <p>6 A. There was no deposition.</p> <p>7 Q. Okay. Without revealing -- I know</p> <p>8 settlements many times can be confidential. Without</p> <p>9 revealing any confidentiality, can you tell us</p> <p>10 anything about the resolution of those two cases?</p> <p>11 A. They were both settled.</p> <p>12 Q. Settled, okay.</p> <p>13 Okay. So no trial; right?</p> <p>14 A. There -- there was no trial and it was for a</p> <p>15 fully disclosed amount.</p> <p>16 Q. Okay. Any other litigation against you</p> <p>17 other than those two cases that we talked about, any</p> <p>18 litigation of any type?</p> <p>19 A. No.</p> <p>20 Q. Have you ever had a disciplinary action</p> <p>21 against you by any medical board?</p> <p>22 A. No.</p> <p>23 Q. Have you ever been arrested or convicted of</p> <p>24 a crime?</p>	<p>1 you were the expert for the defense on the urinary</p> <p>2 incontinence after the vaginal delivery? Do you</p> <p>3 remember a name?</p> <p>4 A. I cannot recall.</p> <p>5 Q. Okay. That would just make it easier to</p> <p>6 reference, but ...</p> <p>7 Okay. In all four of these cases, the</p> <p>8 Cavness case, the Garcia case, the Ramirez case and</p> <p>9 the case involving urinary incontinence after vaginal</p> <p>10 delivery, all four of those cases you were retained by</p> <p>11 the defense; correct?</p> <p>12 A. That's correct.</p> <p>13 Q. You've never testified for the plaintiff as</p> <p>14 an expert; is that right?</p> <p>15 A. I have not testified for the -- for a</p> <p>16 plaintiff. I have given opinions as part of the State</p> <p>17 of Florida Prosecution Unit, which is actually known</p> <p>18 as the Department of Health, Department of Health now.</p> <p>19 It's work that I have done for years for the</p> <p>20 Department of Health.</p> <p>21 Q. Are these like criminal investigations into</p> <p>22 doctors or what -- what is it?</p> <p>23 A. You know, that's why they eliminated the</p> <p>24 Prosecution Unit name because it sounds criminal, so</p>
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<p>1 A. No.</p> <p>2 Q. Okay. We discussed -- okay. Other than</p> <p>3 being retained in the Garcia case as an expert and in</p> <p>4 this -- in the case where you were retained as an</p> <p>5 expert that you mentioned before where you did a</p> <p>6 deposition, have you ever been retained as an expert</p> <p>7 in litigation, other than those two instances you've</p> <p>8 already mentioned?</p> <p>9 MR. SNELL: Hold on, hold on. I'm going to</p> <p>10 instruct you. To the extent you have not been</p> <p>11 disclosed, you should be mindful of that and not</p> <p>12 identify those cases. To the extent you have not</p> <p>13 been disclosed, either by deposition, expert</p> <p>14 report, doing an IME of the plaintiff, under the</p> <p>15 rules, depending upon where you may have been</p> <p>16 retained, that is confidential information.</p> <p>17 A. I gave testimony on Cavness.</p> <p>18 Q. (By Mr. De La Cerda) Okay. Other than</p> <p>19 Cavness, Garcia and then this other case involving</p> <p>20 urinary incontinence after vaginal delivery, any</p> <p>21 other cases where you've been designated as an</p> <p>22 expert?</p> <p>23 A. On -- on Ramirez.</p> <p>24 Q. Right. Is there a name to the case where</p>	<p>1 now we all understand that it's -- it's any complaints</p> <p>2 that have been brought against a physician in my -- in</p> <p>3 my specialty, I and the board feels that needs to be</p> <p>4 reviewed, I review.</p> <p>5 Q. Okay. And how long have you been doing</p> <p>6 that?</p> <p>7 A. Close to 15 years.</p> <p>8 Q. 15 years. Okay.</p> <p>9 Let's talk briefly about your role as a</p> <p>10 consultant for Ethicon outside of litigation. Okay?</p> <p>11 So this word "litigation" is not contemplated, this is</p> <p>12 just your role as a consultant in what -- helping out</p> <p>13 what Ethicon does in its normal business. Okay?</p> <p>14 So, first of all, in the past, you have been</p> <p>15 hired as a consultant for Ethicon; correct?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. And do you recall when you were first</p> <p>18 hired as a consultant for Ethicon?</p> <p>19 A. It may have been just after the year 2000,</p> <p>20 2002. I don't recall the specific year.</p> <p>21 Q. Okay. But early 2000s?</p> <p>22 A. About -- about that time.</p> <p>23 Q. Okay. And what was the purpose of you being</p> <p>24 hired on as a consultant when you first started?</p>

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<p>1 A. Initially, I was given the opportunity to --</p> <p>2 to dissect cadavers and to put together the anatomy</p> <p>3 for the dissection in specimens as it would apply to</p> <p>4 the use of products.</p> <p>5 Q. Okay. So I'm having a little trouble</p> <p>6 understanding what that might be. Explain to me what</p> <p>7 you would do, then, on a typical day involving that</p> <p>8 particular role.</p> <p>9 A. It changed. It changed over the -- over the</p> <p>10 years. I started dissecting and teaching and being</p> <p>11 involved with my peers on how to use the different</p> <p>12 products and it was just an interest that I -- that I</p> <p>13 had very early in my career about surgical anatomy.</p> <p>14 So I just expanded that and I was given the</p> <p>15 opportunity while -- I was given instruments to work</p> <p>16 in the gallery.</p> <p>17 Q. Okay. Did you have a title when you first</p> <p>18 began as a consultant for Ethicon?</p> <p>19 A. No.</p> <p>20 Q. Okay. Were there defined duties that you</p> <p>21 had when you first started out as a consultant?</p> <p>22 MR. SNELL: Form.</p> <p>23 A. No, nothing -- nothing that was defined as</p> <p>24 different task.</p>	<p>1 Q. Okay. So is that 2012, approximately?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. So I guess that's about ten years of</p> <p>4 acting as a consultant; is that fair?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. So the manner in which your role as a</p> <p>7 consultant changed, was it really in -- in regard to</p> <p>8 the products themselves, what kind of product you were</p> <p>9 teaching, or is there some other way in which it</p> <p>10 changed?</p> <p>11 A. It changed. It changed based on what --</p> <p>12 whatever was understood that there was a need.</p> <p>13 Q. Okay. Can you give me some examples?</p> <p>14 A. Initially, it was seeing the products, how</p> <p>15 they would work, and nothing -- nothing in terms of</p> <p>16 experiment or research and development. It was more</p> <p>17 on how -- how to reproduce their use in the -- in the</p> <p>18 operating room.</p> <p>19 Q. Mm-hmm.</p> <p>20 A. And then I was able to -- to see -- to see</p> <p>21 how -- how the products were actually implemented</p> <p>22 in -- in the surgical environment. And there was a</p> <p>23 time in which I would just see other surgeons that</p> <p>24 were consultants. And then there was a time in which</p>
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<p>1 Q. (By Mr. De La Cerda) Okay. They didn't</p> <p>2 have, like, a job description that was given to you</p> <p>3 when you first started?</p> <p>4 A. No.</p> <p>5 Q. Okay. And so in this role involving</p> <p>6 dissecting cadavers, where you were teaching other</p> <p>7 peers about how to use the Ethicon products, was that</p> <p>8 a role that remained consistent throughout your time</p> <p>9 as a consultant for Ethicon or did it change over</p> <p>10 time?</p> <p>11 A. It changed based on the needs that they had,</p> <p>12 for what -- what they understood was my expertise.</p> <p>13 Q. Okay. So let's do this. So the beginning</p> <p>14 is approximately the beginning of the 2000s. Has that</p> <p>15 con- -- has that role as a consultant for Ethicon</p> <p>16 ended or do you continue to be a consultant for</p> <p>17 Ethicon?</p> <p>18 A. No, I don't consult with them anymore beyond</p> <p>19 the legal.</p> <p>20 Q. And so when did your role as a consultant</p> <p>21 end?</p> <p>22 A. Just -- just about the time that the</p> <p>23 products -- the prolapse products were</p> <p>24 decommercialized.</p>	<p>1 I would go to and meet with -- with a group at Ethicon</p> <p>2 and give a conference on anatomy or I would take them</p> <p>3 to the lab and show them the anatomy.</p> <p>4 Q. Mm-hmm.</p> <p>5 A. And then there was a time in which I</p> <p>6 actually wrote a manual of how to dissect -- dissect a</p> <p>7 specimen, make the best of that dissection.</p> <p>8 Q. Okay. But tell me about this manual. What</p> <p>9 is it that you'd be dissecting -- so tell me, what was</p> <p>10 the content of this manual?</p> <p>11 A. The labs -- the labs using specimens are</p> <p>12 very unique and they're very -- they're very</p> <p>13 expensive.</p> <p>14 Q. Okay.</p> <p>15 A. And the whole setup of getting a good</p> <p>16 specimen. And what we call "specimens" is a portion</p> <p>17 of a person and there -- there are certain things that</p> <p>18 we have to follow over the years, over the last 25</p> <p>19 years that I have learned dissecting and understanding</p> <p>20 the anatomy. One of the most complex anatomies that</p> <p>21 you can have in any other -- other part of the body.</p> <p>22 So when we -- when we did this and there's -- my</p> <p>23 interest was that, and I verbalized that, that we</p> <p>24 could make the best use of these specimens in the lab.</p>

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<p>1 Q. Mm-hmm.</p> <p>2 A. And not only that it would be -- it would be</p> <p>3 the best use, but also that it would be a systematic</p> <p>4 approach in the same way that first-year medical</p> <p>5 students are taught anatomy.</p> <p>6 Q. Mm-hmm. Okay.</p> <p>7 A. So to get -- to make that organized and to</p> <p>8 make that systematic and to make that consistent, then</p> <p>9 there was -- there was a proposal for a manual. That</p> <p>10 was just one part of -- of what could be done in -- in</p> <p>11 the lab -- laboratory.</p> <p>12 Q. And this was a manual that was done for</p> <p>13 Ethicon; right?</p> <p>14 A. It was done for -- for them, but I think it</p> <p>15 was -- there were other -- other considerations</p> <p>16 beyond -- beyond anatomy and probably did not get</p> <p>17 developed, but I got the -- I got the opportunity to</p> <p>18 take my pictures and actually put it in -- on my thumb</p> <p>19 drive with presentations, which you're going to be</p> <p>20 requesting.</p> <p>21 Q. Okay. Are these cadaver specimens, they're</p> <p>22 reused for purposes of teaching doctors how to do --</p> <p>23 how to, for example, implant Ethicon's products;</p> <p>24 right?</p>	<p>1 have you now explained all the various things that you</p> <p>2 did as a consultant on behalf of Ethicon?</p> <p>3 MR. SNELL: Form.</p> <p>4 A. I -- I actually look at presentations. In</p> <p>5 addition to, I look at presentations. I would make a</p> <p>6 presentation to -- to different groups within Ethicon.</p> <p>7 Q. (By Mr. De La Cerda) You would do</p> <p>8 presentations for other physicians about Ethicon's</p> <p>9 products; is that correct?</p> <p>10 A. About Ethicon products and about the</p> <p>11 condition itself.</p> <p>12 Q. Okay. And did the presentations that you do</p> <p>13 to other doctors for Ethicon include TVT, TVT-O,</p> <p>14 Gynemesh, Prolift and Prosima?</p> <p>15 A. It was TVT-O, TVT-Secur, Gynemesh, Prosima,</p> <p>16 and Prolift.</p> <p>17 Q. Any reason why you didn't do presentations</p> <p>18 on regular TVT or TVT-R?</p> <p>19 A. I had a -- I had a preference for the</p> <p>20 transobturator slings.</p> <p>21 Q. Had you used in the past a TVT Retropubic</p> <p>22 for your patients?</p> <p>23 A. Yes.</p> <p>24 Q. And why is it that you preferred the TVT-O</p>
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<p>1 A. Well, cadavers are used in sections and,</p> <p>2 obviously, we're going to -- we're going to use a</p> <p>3 section that pertains to the procedure that we're</p> <p>4 doing and they -- they form the basis of teaching</p> <p>5 anatomy from the first year of medical school.</p> <p>6 Q. Do they -- do the cadaver -- I guess the</p> <p>7 portions of the cadaver that are used to present how</p> <p>8 to implant products, do they eventually get used, to a</p> <p>9 certain extent, to where, okay, we can't use this</p> <p>10 cadaver anymore, like it's been used too much for this</p> <p>11 particular presentation?</p> <p>12 A. You can -- you can always make -- make the</p> <p>13 best of what you're examining. So, yeah, if there is</p> <p>14 a portion that is used, you can always go to different</p> <p>15 things that you can teach from the -- from the</p> <p>16 cadaver. That's highly dependent on the condition of</p> <p>17 the cadaver.</p> <p>18 Q. Yeah.</p> <p>19 A. It's highly dependent on how it was</p> <p>20 prepared. It's highly dependent on how those</p> <p>21 individuals that are doing the dissection know how to</p> <p>22 do it.</p> <p>23 Q. Okay. Okay. So going back to your role as</p> <p>24 a consultant for Ethicon and what it is that you did,</p>	<p>1 over the TVT?</p> <p>2 A. I felt I could do the same with less risk.</p> <p>3 Q. And what risk are you specifically talking</p> <p>4 about?</p> <p>5 A. Getting to the bladder. Very rare, but</p> <p>6 potential getting to the bowel and getting to a major</p> <p>7 blood vessel.</p> <p>8 Q. You've testified before that you've made --</p> <p>9 you've made about \$100,000 a year as a consultant for</p> <p>10 Ethicon; is that right?</p> <p>11 A. That -- I may have testified to that number,</p> <p>12 yes.</p> <p>13 Q. Okay. And so if we're talking about ten</p> <p>14 years, we're talking about approximately a million</p> <p>15 dollars you made as a consultant for Ethicon; correct?</p> <p>16 MR. SNELL: Form.</p> <p>17 A. No, it doesn't -- doesn't get to that</p> <p>18 because it wasn't -- it wasn't like a salary. It was</p> <p>19 in a -- in a need and there were years that it was</p> <p>20 \$3,000.</p> <p>21 Q. (By Mr. De La Cerda) Do you have an</p> <p>22 approximation of how much you made total as a</p> <p>23 consultant for Ethicon?</p> <p>24 A. I -- I think the largest and the best year,</p>

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<p>1 most active year, I may have done about 100. But</p> <p>2 that -- that's probably one or two years.</p> <p>3 Q. Do you have a range, total, for all the</p> <p>4 years that you acted as a consultant for Ethicon?</p> <p>5 A. Never -- never really counted.</p> <p>6 Q. Do you have any documentation of that, of</p> <p>7 what the numbers might be?</p> <p>8 A. My 1099s that I receive or my tax returns.</p> <p>9 Q. Okay. And if Ethicon has records of that,</p> <p>10 you'd, of course, defer to whatever those records say;</p> <p>11 right?</p> <p>12 MR. SNELL: Objection, form, foundation.</p> <p>13 A. As -- as long as they correlate with my</p> <p>14 1099.</p> <p>15 Q. (By Mr. De La Cerda) Right. So if they</p> <p>16 had records of the 1099s, which I assume they do,</p> <p>17 you would defer to whatever those numbers are;</p> <p>18 right?</p> <p>19 A. I -- I would defer to that.</p> <p>20 Q. When you've presented on Ethicon's products,</p> <p>21 where have those presentations occurred,</p> <p>22 geographically?</p> <p>23 A. You know, it happened mostly here either in</p> <p>24 Florida or in New Jersey. Occasionally, I would go</p>	<p>1 specifics on which hotel we could stay and -- and no</p> <p>2 first class traveling, and there was compensation, if</p> <p>3 we would drive, for the miles --</p> <p>4 Q. Okay.</p> <p>5 A. -- and there were also some -- some limits</p> <p>6 on what we could spend on food, although most of the</p> <p>7 time food was provided there.</p> <p>8 Q. Do you know whether Ethicon believed you to</p> <p>9 be a good preceptor or teacher on its TVT products?</p> <p>10 A. I -- I think that they visualized me as a</p> <p>11 good surgeon with good common surgical sense.</p> <p>12 Q. And I just used the term "preceptor," I need</p> <p>13 to make sure that's understood. Could you explain to</p> <p>14 us what the term -- what your understanding of the</p> <p>15 term "preceptor" is?</p> <p>16 A. The preceptor is -- is a term that was, I</p> <p>17 believe, from mostly the marketing people. I never</p> <p>18 really saw myself as a preceptor.</p> <p>19 Q. Mm-hmm.</p> <p>20 A. I saw myself as a surgeon. And if you ask</p> <p>21 any of my colleagues, they don't see me as a</p> <p>22 preceptor. Through the course -- through the years, I</p> <p>23 have seen doctors that have seen me for every single</p> <p>24 product and we always ended up talking about the same</p>
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<p>1 to -- to other cities, Austin, Toronto, Dallas,</p> <p>2 Boston. Never -- never too -- never too far. I -- I</p> <p>3 made that decision that I wasn't going to go, let's</p> <p>4 say, to the Northwest or California maybe once because</p> <p>5 I have a practice that I have to take care of.</p> <p>6 Q. Right. I guess you have the advantage, too,</p> <p>7 of being in Miami, doctors would want to come to you</p> <p>8 for the -- were there many presentations here in</p> <p>9 Miami, too?</p> <p>10 A. There -- there were -- yeah, there were some</p> <p>11 in Miami, absolutely.</p> <p>12 Q. Okay. When the presentations were out of</p> <p>13 town, Ethicon, of course, covered your -- your meals,</p> <p>14 your lodging, your transportation; right?</p> <p>15 A. With- -- within the -- within the range that</p> <p>16 was specified for that kind of traveling.</p> <p>17 Q. How was that done? How was the range</p> <p>18 specified?</p> <p>19 A. We -- we were required to take a course on</p> <p>20 guidelines for -- as consultants for any kind of</p> <p>21 industry.</p> <p>22 Q. Mm-hmm. And do you recall any of what those</p> <p>23 guidelines were?</p> <p>24 A. I -- I do recall there was -- there were</p>	<p>1 thing, the anatomy and the surgery.</p> <p>2 Q. Mm-hmm. And so preceptor, I guess that's</p> <p>3 used as some version of saying that someone's a</p> <p>4 teacher; is that right?</p> <p>5 A. I -- I think it was an internal term for --</p> <p>6 for them, preceptor, and it's -- it doesn't get to the</p> <p>7 level of a teacher or a professor, it doesn't have</p> <p>8 that -- that responsibility. It doesn't have -- it</p> <p>9 has mostly the role of showing something, of</p> <p>10 demonstrating.</p> <p>11 Q. Okay. Do you know whether Ethicon ever</p> <p>12 criticized the way in which you taught other</p> <p>13 physicians in preceptorships?</p> <p>14 A. They -- they did not have a specific</p> <p>15 criticism and they -- they would ask, whenever they</p> <p>16 would bring someone to see me operating, that they had</p> <p>17 a -- that the doctors could get to see as much as they</p> <p>18 could see in terms of the variety of procedures, but,</p> <p>19 obviously, that -- the cases are what the cases are.</p> <p>20 Q. Yeah.</p> <p>21 A. You show what you have.</p> <p>22 Q. Ethicon -- I guess, in other words, Ethicon</p> <p>23 never said -- made you personally aware of any</p> <p>24 specific criticisms of any type of the manner in which</p>

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<p>1 you were teaching other doctors how to perform these</p> <p>2 procedures; right?</p> <p>3 MR. SNELL: Form.</p> <p>4 A. There -- there was -- it was a relationship</p> <p>5 with -- with a lot of respect for what I did, for what</p> <p>6 I brought to the -- to their table.</p> <p>7 Q. (By Mr. De La Cerda) Okay. So the answer</p> <p>8 is no, you never became aware of any criticisms;</p> <p>9 right?</p> <p>10 A. No.</p> <p>11 Q. In August of 2011, you decided to stop</p> <p>12 preceptorships due to the FDA situation; correct?</p> <p>13 A. I -- I -- there was a communication that</p> <p>14 said we -- we need to look at this and we need to look</p> <p>15 at what the FDA is saying, and everybody needs to be</p> <p>16 on the same wavelength.</p> <p>17 Q. Mm-hmm. And so what -- how long did that</p> <p>18 last, that decision to suspend or interrupt your</p> <p>19 preceptorships?</p> <p>20 A. I don't -- I don't remember exactly how --</p> <p>21 how long did it last or if I ever went back and did a</p> <p>22 consultation in other -- other regards. It's -- it</p> <p>23 was just a gen- -- probably a general concern from all</p> <p>24 sides.</p>	<p>1 Q. (By Mr. De La Cerda) Do you remember ever</p> <p>2 discussing this FDA issue with doctors during a</p> <p>3 consultation on behalf of Ethicon?</p> <p>4 A. I -- I don't remember that.</p> <p>5 Q. Okay. Do you remember discussing this issue</p> <p>6 at all with any doctors in regard to Ethicon products?</p> <p>7 MR. SNELL: Objection, form.</p> <p>8 Go ahead.</p> <p>9 A. I don't -- I don't remember specifics of</p> <p>10 talking to a specific doctor or being at a conference</p> <p>11 just talking about -- about this.</p> <p>12 I don't even remember if it was 2007, 2008,</p> <p>13 or -- I don't remember which time frame it was. I</p> <p>14 am -- you know, I became aware of this, that I say at</p> <p>15 one point we need to stop or we need to review, we</p> <p>16 need to revise it, or we need to look at it, but it</p> <p>17 was never like, oh, no, I'm not teaching anymore, I'm</p> <p>18 not demonstrating anymore for you.</p> <p>19 Q. (By Mr. De La Cerda) Mm-hmm.</p> <p>20 A. That's what I can recall. That's the best</p> <p>21 of my recollection right now.</p> <p>22 Q. Why is it important when the FDA puts out a</p> <p>23 warning, like they did in 2011, to investigate and</p> <p>24 look into what -- the reason behind the warning?</p>
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<p>1 Q. Okay. Just to make sure. So you're unsure</p> <p>2 whether, in August of 2011 when you decided to stop</p> <p>3 the preceptorships due to the FDA concern, you're</p> <p>4 unsure whether you went back to consulting for Ethicon</p> <p>5 after that point?</p> <p>6 A. Yeah, I --</p> <p>7 MR. SNELL: Objection to form.</p> <p>8 Go ahead.</p> <p>9 A. -- I did -- I did not cut completely at that</p> <p>10 time and actually it was -- it was me relating, I</p> <p>11 believe, to Bob Zipfel, who was the professional</p> <p>12 education manager --</p> <p>13 Q. (By Mr. De La Cerda) You said Bob Zipfel?</p> <p>14 A. Zipfel, Z-i-p-f-e-l.</p> <p>15 -- relating that we -- we need to get clear</p> <p>16 on the -- on the message and we need to include</p> <p>17 whatever is out there and be transpiring about it.</p> <p>18 Q. And so what was it that you decided, along</p> <p>19 with Ethicon, to make clear about the message</p> <p>20 involving this issue?</p> <p>21 MR. SNELL: Objection, form, Ethicon.</p> <p>22 A. As far as I remember from my side, it was</p> <p>23 let's -- let's look at this. It was -- that's more of</p> <p>24 the attitude that I can recall.</p>	<p>1 MR. SNELL: Form.</p> <p>2 A. It's because the results and the clinical</p> <p>3 experience that we're getting was different from what</p> <p>4 we were seeing in those -- in those reports.</p> <p>5 Q. (By Mr. De La Cerda) Okay. So the FDA</p> <p>6 warning came out in July of 2011, was that a</p> <p>7 surprise to you?</p> <p>8 A. It was -- it was a surprise in 2008 and it</p> <p>9 was in 2011. What I -- what I thought is evidence is</p> <p>10 going to come in and is going to show -- it's going to</p> <p>11 solve this difference that a group of doctors may have</p> <p>12 with other group of doctors.</p> <p>13 Q. You're familiar with the Abbott study that</p> <p>14 came out -- it came out probably in 2014, I think.</p> <p>15 Abbott -- the lead author is Abbott, Mickey Karram is</p> <p>16 one of the authors as well. And one of the</p> <p>17 discussions they have is that many times when -- I</p> <p>18 think about half the time, at least -- when a patient</p> <p>19 has a complication involving a mesh implant, whether</p> <p>20 it be a sling or a pelvic organ prolapse mesh, they do</p> <p>21 not return to the physician that implanted it.</p> <p>22 Are you aware of that phenomenon?</p> <p>23 MR. SNELL: I'm going to object to the</p> <p>24 foundation on that.</p>

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<p style="text-align: right;">Page 30</p> <p>1 Go ahead.</p> <p>2 A. I -- I've heard about that. I never</p> <p>3 believed that that's the case.</p> <p>4 Q. (By Mr. De La Cerda) Okay. And why is</p> <p>5 that?</p> <p>6 A. Because of my own experience, because of</p> <p>7 my -- the experience that I have heard from my</p> <p>8 colleagues. That's -- that's not what our experience</p> <p>9 is.</p> <p>10 You -- you may have a small percentage that</p> <p>11 may not come back, but in my community, for example,</p> <p>12 we all know, we all communicate. There are four, five</p> <p>13 board-certified female pelvic medicine in the whole</p> <p>14 stretch all the way to Boca from here. We know each</p> <p>15 other and -- and the doctors also communicate with us,</p> <p>16 so there is a lot of communication there.</p> <p>17 If there is a loss to follow up, it might be</p> <p>18 on the clinic setting, when you have these clinics,</p> <p>19 other -- other types of settings, but not in the</p> <p>20 private-practice setting.</p> <p>21 Q. If a patient went to go receive treatment</p> <p>22 for a complication in a different city that's</p> <p>23 something like Dallas, for example, would you</p> <p>24 necessarily find out about that?</p>	<p style="text-align: right;">Page 32</p> <p>1 study? Like have you actually reviewed it?</p> <p>2 A. I -- I did not read that study complete, no.</p> <p>3 Q. Okay. Then I'm going to move on to another</p> <p>4 subject then.</p> <p>5 Going back to acting as a consultant, have</p> <p>6 you ever acted as a consultant for any other</p> <p>7 pharmaceutical or medical device company?</p> <p>8 A. For pharmaceuticals, I work for ALZA</p> <p>9 Pharmaceuticals.</p> <p>10 Q. Is that --</p> <p>11 A. A-L-Z-A. When they came -- they came in</p> <p>12 with a new anticholinergic.</p> <p>13 Q. I'm sorry, what is that?</p> <p>14 A. ALZA, A-L-Z-A, Pharmaceuticals.</p> <p>15 Q. And the drug?</p> <p>16 A. It was Ditropan XL.</p> <p>17 Q. Ditropan XL.</p> <p>18 And what was that drug for?</p> <p>19 A. For overactive bladder.</p> <p>20 Q. How long did you work as a consultant for</p> <p>21 ALZA Pharmaceutical?</p> <p>22 A. About two years.</p> <p>23 Q. And do you recall approximately when that</p> <p>24 was?</p>
<p style="text-align: right;">Page 31</p> <p>1 A. I may not -- I may not find out, but I know</p> <p>2 that most of the time it's not even dependent on the</p> <p>3 patient. They -- they come and they communicate with</p> <p>4 me. I've had patients that have gone to New York,</p> <p>5 they come back and tell me this was my experience.</p> <p>6 Q. You mentioned something interesting because</p> <p>7 you're -- and I hear this from physicians every time.</p> <p>8 I think this is our natural inclination.</p> <p>9 You mentioned in your experience you haven't</p> <p>10 seen that happen. Ultimately, you would agree that</p> <p>11 your personal experience on that issue, on whether</p> <p>12 people come back to the primary physician or not, is,</p> <p>13 at best, only anecdotal. Do you agree with that?</p> <p>14 A. It's -- it is definitely a portion that is</p> <p>15 anecdotal. I do talk to so many of my colleagues and</p> <p>16 if it's anecdotal, it repeats a lot.</p> <p>17 Q. Yeah, I get that. I mean, here you are in a</p> <p>18 community where you do actually know all these</p> <p>19 physicians that do this thing and if the general</p> <p>20 consensus is that this is what's happening, it can</p> <p>21 certainly feel like this is the reality of it. But</p> <p>22 ultimately we've got a study that was done that looked</p> <p>23 at many people -- by the way -- strike that.</p> <p>24 Are you familiar with this study, the Abbott</p>	<p style="text-align: right;">Page 33</p> <p>1 A. It was when I was starting the urogyne</p> <p>2 center here, so it may have been '96, '97.</p> <p>3 Q. Any other medical device or pharmaceutical</p> <p>4 companies that you've acted as a consultant for, other</p> <p>5 than ALZA and Ethicon?</p> <p>6 A. I -- oh, I worked for Ethicon on the</p> <p>7 laparoscopy area around 1994, internationally.</p> <p>8 Q. Was that just for one year?</p> <p>9 A. A year, year and a half, yes.</p> <p>10 Q. Any other consulting work for pharmaceutical</p> <p>11 or medical device companies?</p> <p>12 A. You know, I may have -- I may have had</p> <p>13 representatives from one or two companies that say I</p> <p>14 want you to go ahead and teach me how my product works</p> <p>15 and -- and teach me how -- how is it that urge</p> <p>16 incontinence is managed.</p> <p>17 And I may say, okay, and some of them may</p> <p>18 give me a check, which I ended up either giving to the</p> <p>19 Residents Fund in Puerto Rico or did something with</p> <p>20 it, but it was something sporadic.</p> <p>21 Q. Would these be some of the other mesh</p> <p>22 manufacturers, like Boston Scientific or American</p> <p>23 Medical Systems, companies like that?</p> <p>24 A. No, I did not -- I -- I never did consulting</p>

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<p style="text-align: right;">Page 34</p> <p>1 for any other company on mesh but Ethicon.</p> <p>2 Q. Do you remem- -- do you recall the names of</p> <p>3 the companies that you did this urge incontinence work</p> <p>4 for?</p> <p>5 A. I think it may have been Detrol or --</p> <p>6 Q. Detrol?</p> <p>7 A. -- Enablex. I don't remember the name of</p> <p>8 the company.</p> <p>9 Q. Okay. And do you recall the approximate</p> <p>10 years that would have happened?</p> <p>11 A. No.</p> <p>12 Q. Okay. Now let's get to the part that's</p> <p>13 always the most tedious. What is it that you brought</p> <p>14 here today with you?</p> <p>15 A. I brought here in compliance with the papers</p> <p>16 served for the subpoena, I brought my CV --</p> <p>17 You have a copy?</p> <p>18 Q. Yes.</p> <p>19 A. -- and a USB, in which I have any file that</p> <p>20 I had on my computer that when I -- when I was at</p> <p>21 Ethicon, I just downloaded my presentations.</p> <p>22 Q. Okay.</p> <p>23 A. And there were some videos of surgeries</p> <p>24 here.</p>	<p style="text-align: right;">Page 36</p> <p>1 Q. Okay. What -- I guess what I would be most</p> <p>2 interested in is what you brought that is not on the</p> <p>3 Reliance List. Because most of -- just about</p> <p>4 everything on the Reliance List we can find.</p> <p>5 And so, first of all, these book chapters,</p> <p>6 are those referenced in the Reliance List, these books</p> <p>7 that you have listed here in -- here in front of us?</p> <p>8 A. No, they're not.</p> <p>9 Q. Okay. So are there particular portions of</p> <p>10 those books that are relevant to your opinions or is</p> <p>11 it the whole book?</p> <p>12 A. I -- I -- there are portions that are</p> <p>13 relevant to the way I see slings and meshes work.</p> <p>14 Q. Okay. Okay. And can you tell us what -- is</p> <p>15 it a chapter? Is it a particular passage or --</p> <p>16 A. They're -- they're chapters.</p> <p>17 Q. Okay. And as far as you know, they are not</p> <p>18 referenced in the Reliance List at all?</p> <p>19 A. They're -- they're not, that's why I brought</p> <p>20 them, and the same with the -- with the USB.</p> <p>21 Q. Okay. So, again, first of all, let's do</p> <p>22 this. Let's separate out the items that are not on</p> <p>23 the Reliance List so we can make sure and mark and</p> <p>24 identify those and -- so let's do that.</p>
<p style="text-align: right;">Page 35</p> <p>1 Q. Okay.</p> <p>2 A. And I brought my biomechanics books and the</p> <p>3 book that Ethicon put together for -- about Gynemesh</p> <p>4 and Prolift, and I did -- the one on Gynemesh is about</p> <p>5 my slides.</p> <p>6 And I -- but all the materials that were</p> <p>7 cited in my report and materials for prolapse, my</p> <p>8 materials for case specifics for tomorrow,</p> <p>9 depositions, and the Prolift monograph.</p> <p>10 Q. Okay. And that's it?</p> <p>11 A. I am missing the white paper on</p> <p>12 hydrodissection. That I could not find at all. I</p> <p>13 will make it my business to provide to you.</p> <p>14 MR. SNELL: Peter, I think we provided --</p> <p>15 there's thumb drives that my office did, too.</p> <p>16 MR. DE LA CERDA: Are those all -- those are</p> <p>17 the case-specific ones?</p> <p>18 MR. SNELL: Case and general.</p> <p>19 Q (By Mr. De La Cerda) Okay. So that we're</p> <p>20 not taxing the court reporter too much on copying</p> <p>21 and the like -- first of all, are the materials that</p> <p>22 you brought, other than the books, are those all</p> <p>23 copies?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 37</p> <p>1 So the books that are here, these are the</p> <p>2 ones not on the Reliance List; right?</p> <p>3 A. Yes, sir.</p> <p>4 Q. And then you've got -- and I'm going to mark</p> <p>5 each of these in a second-- the USB that you brought;</p> <p>6 correct?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. Anything else, other than those and</p> <p>9 other than the case-specific USBs that you brought,</p> <p>10 anything else that is not on the Reliance List?</p> <p>11 A. The only one missing that I -- that I didn't</p> <p>12 bring today that I'm -- I made my best effort to bring</p> <p>13 you is the white paper that I wrote on hydrodissection</p> <p>14 along with Dr. Lucente and -- yeah.</p> <p>15 MR. DE LA CERDA: Okay. So as far as</p> <p>16 marking these, anything -- any particular way you</p> <p>17 want to -- you want to do this, Burt?</p> <p>18 MR. SNELL: It doesn't matter. This stuff</p> <p>19 here is like all general stuff, from his general</p> <p>20 reports and the Reliance List, and I think it's</p> <p>21 probably duplicative of the hard copies and also</p> <p>22 specific citations in the materials. I was just</p> <p>23 trying to sort out --</p> <p>24 MR. DE LA CERDA: The case-specific --</p>

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<p>1 MR. SNELL: We sent so many cases to the</p> <p>2 thumb drives and stuff like that over time. This</p> <p>3 is general. If you want a copy -- I don't even</p> <p>4 know what's on these. I know they reproduced --</p> <p>5 I think they were supposed to reproduce the</p> <p>6 materials list, but I haven't checked them to</p> <p>7 see.</p> <p>8 MR. DE LA CERDA: Okay.</p> <p>9 MR. SNELL: I mean, I agree, I think you</p> <p>10 ought to mark definitely the stuff that was just</p> <p>11 kind of general -- general impression, the</p> <p>12 general stuff that he brought.</p> <p>13 MR. DE LA CERDA: Yeah.</p> <p>14 MR. SNELL: And if you want to -- mark</p> <p>15 whatever you want, you know.</p> <p>16 MR. DE LA CERDA: Yeah.</p> <p>17 MR. SNELL: These just have his reports and,</p> <p>18 like he said, everything that he cited -- here's</p> <p>19 some articles in here. You can tell him, those</p> <p>20 are probably cited within there.</p> <p>21 THE WITNESS: This is cited and this is</p> <p>22 cited, this is cited, too. This is a monograph.</p> <p>23 These two are new. These two are new.</p> <p>24 MR. SNELL: Is there anything in this?</p>	<p>1 mark that.</p> <p>2 A. This -- this is all medical literature.</p> <p>3 Q. Okay. So of the stuff that we've got here,</p> <p>4 what -- we have a stack here that's medical</p> <p>5 literature.</p> <p>6 A. Yes.</p> <p>7 Q. Are any of the binders medical literature?</p> <p>8 A. All of it.</p> <p>9 MR. SNELL: It's all literature. It's the</p> <p>10 stuff cited directly in his reports.</p> <p>11 MR. DE LA CERDA: Okay.</p> <p>12 MR. SNELL: Do you use footnotes or --</p> <p>13 THE WITNESS: Yes, I did. Every footnote --</p> <p>14 MR. SNELL: It should correspond in here.</p> <p>15 MR. DE LA CERDA: And then this stack here</p> <p>16 that I've got is all not in the Reliance List;</p> <p>17 right?</p> <p>18 MR. SNELL: I will say with the -- I'm about</p> <p>19 99 percent sure that this would have been. The</p> <p>20 Prolift monograph, surgeons' monograph is</p> <p>21 definitely on his materials list and he's</p> <p>22 referenced that before. This is his actual --</p> <p>23 this is your actual preceptor book. I don't know</p> <p>24 what you called it.</p>
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<p>1 Here.</p> <p>2 THE WITNESS: This is not cited. Cited,</p> <p>3 cited.</p> <p>4 MR. DE LA CERDA: I think we're going to</p> <p>5 have to do this the long way.</p> <p>6 Q. (By Mr. De La Cerda) Okay. All right.</p> <p>7 So here's what I want to do. Just to make --</p> <p>8 because I don't want to miss anything, because it</p> <p>9 looks like you might have some newer stuff. Maybe</p> <p>10 you looked at some additional research or something</p> <p>11 and found some newer stuff, but what I want to do</p> <p>12 is, let's just -- I want to stack it by category and</p> <p>13 then I'll mark each stack.</p> <p>14 So the easiest way to do it, for me, at</p> <p>15 least, is do it by -- you know, we do ours like this,</p> <p>16 too. We're going to do it by stacks that involve</p> <p>17 certain subject matters, like, for example, everything</p> <p>18 you've brought today that is a medical literature,</p> <p>19 let's put that all into one stack and I'm going to</p> <p>20 mark that. Okay? And then everything you brought</p> <p>21 today that would be Ethicon documents, internal</p> <p>22 documents, we'll -- we'll mark that. And then</p> <p>23 everything you brought today that would be depositions</p> <p>24 or testimony that you reviewed and relied on, we'll</p>	<p>1 THE WITNESS: It's the book that Ethicon</p> <p>2 made on Gynemesh and Prolift and they -- and I</p> <p>3 put together the first one.</p> <p>4 MR. SNELL: I think that that's on his</p> <p>5 materials list, too, but just in case, I mean he</p> <p>6 brought that. That's his actual one.</p> <p>7 The Surgeons' Resource Monograph, I know for</p> <p>8 a fact, has got to be on there.</p> <p>9 MR. DE LA CERDA: So what I'm going to do</p> <p>10 is --</p> <p>11 MR. SNELL: He brought that. That's</p> <p>12 obviously his originals.</p> <p>13 Q. (By Mr. De La Cerda) I'm not going to</p> <p>14 mark these, I'm just going to identify them.</p> <p>15 So today you brought with you the Gynecare</p> <p>16 Prolift and the Gynecare Gynemesh Preceptor</p> <p>17 Presentation Kit; correct?</p> <p>18 A. Yes.</p> <p>19 Q. And these are your -- this is your original?</p> <p>20 A. Yes.</p> <p>21 Q. Now, do you have this available at all</p> <p>22 electronically?</p> <p>23 A. No.</p> <p>24 MR. DE LA CERDA: Okay. Do you know if</p>

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<p style="text-align: right;">Page 42</p> <p>1 these are available electronically?</p> <p>2 THE WITNESS: There might be a CD.</p> <p>3 MR. SNELL: I think if you open the inside</p> <p>4 cover, there are CDs.</p> <p>5 THE WITNESS: There might be a CD there,</p> <p>6 yes.</p> <p>7 MR. DE LA CERDA: Because what I would like</p> <p>8 to do is get a copy of this, just electronically,</p> <p>9 because this -- so it's not copied -- so the</p> <p>10 court reporter doesn't have to copy it.</p> <p>11 So how do you want to do that?</p> <p>12 MR. SNELL: Do you want -- can I take it?</p> <p>13 THE WITNESS: Yeah. Send it back because</p> <p>14 it's the only one I have.</p> <p>15 MR. SNELL: I mean, there's two ways. We</p> <p>16 can either have the court reporter do it and then</p> <p>17 it's going through multiple people's hands or if</p> <p>18 you give it to me, I'll make color copies of</p> <p>19 everything, the cover, the back, the pages, and</p> <p>20 then I'll burn the CDs.</p> <p>21 MR. DE LA CERDA: Okay.</p> <p>22 MR. SNELL: I'll basically give you an exact</p> <p>23 copy of what you're holding and then I'll</p> <p>24 actually make a copy for myself, because I don't</p>	<p style="text-align: right;">Page 44</p> <p>1 A. Yes.</p> <p>2 Q. And this is medical literature that happens</p> <p>3 not to be on the Reliance List; correct?</p> <p>4 A. That's correct.</p> <p>5 MR. DE LA CERDA: So I'm marking that as</p> <p>6 Exhibit 3.</p> <p>7 (Plaintiff's Exhibit No. 3 was marked for</p> <p>8 identification.)</p> <p>9 MR. SNELL: Just for the record, since,</p> <p>10 obviously, my firm was the one who made the</p> <p>11 Reliance List, I do believe that one of those may</p> <p>12 be on there.</p> <p>13 MR. DE LA CERDA: Okay.</p> <p>14 MR. SNELL: Like the ACOG committee opinion</p> <p>15 on vaginal prolapse mesh, I'm pretty sure that's</p> <p>16 on the materials list, if I even have his</p> <p>17 materials list.</p> <p>18 You can keep doing that.</p> <p>19 MR. DE LA CERDA: Okay.</p> <p>20 MR. SNELL: But I'm pretty sure that would</p> <p>21 have been sent.</p> <p>22 MR. DE LA CERDA: Prosima IFU, I'm sure that</p> <p>23 was on the Reliance List.</p> <p>24 MR. SNELL: All that stuff is on the</p>
<p style="text-align: right;">Page 43</p> <p>1 have a copy of that exact one, and then I'll give</p> <p>2 it back to the doctor.</p> <p>3 MR. DE LA CERDA: Okay. So then that --</p> <p>4 MR. SNELL: Let's make a record for that, a</p> <p>5 note for that.</p> <p>6 MR. DE LA CERDA: So for the record, then,</p> <p>7 that will be Exhibit 1. I'm just going to put</p> <p>8 this here for now.</p> <p>9 MR. SNELL: I will make a note I need to</p> <p>10 take that and copy it.</p> <p>11 MR. DE LA CERDA: So for the record,</p> <p>12 Exhibit 1 is the Gynecare Prolift and Gynecare</p> <p>13 Gynemesh PS Preceptor Presentation Kit.</p> <p>14 (Plaintiff's Exhibit No. 1 was marked for</p> <p>15 identification.)</p> <p>16 MR. DE LA CERDA: Exhibit 2 is going to be</p> <p>17 Dr. Sepulveda's original Prolift Surgeon's</p> <p>18 Resource Monograph.</p> <p>19 (Plaintiff's Exhibit No. 2 was marked for</p> <p>20 identification.)</p> <p>21 Q. (By Mr. De La Cerda) Now, Exhibit 3, I'm</p> <p>22 going to mark, these are -- this is medical</p> <p>23 literature that you've gathered, Dr. Sepulveda;</p> <p>24 correct?</p>	<p style="text-align: right;">Page 45</p> <p>1 Reliance List.</p> <p>2 THE WITNESS: I can take that back.</p> <p>3 MR. SNELL: All the professional education</p> <p>4 slides, those are on there.</p> <p>5 Q. (By Mr. De La Cerda) All of these are</p> <p>6 also on the Reliance List; right? Okay. So I'm not</p> <p>7 going to mark those.</p> <p>8 And then, now, books. Let's go through each</p> <p>9 of these.</p> <p>10 First of all, I'm looking at a book called</p> <p>11 "Biomechanics: Mechanical Properties of Living</p> <p>12 Tissues," the Second Edition, published by Springer</p> <p>13 and the author is Y.C. Fung, F-u-n-g.</p> <p>14 Do you have specific chapters that you can</p> <p>15 identify within this book that you rely on?</p> <p>16 A. Yes. Chapter 7.</p> <p>17 Q. Okay. Any others?</p> <p>18 A. No, 7.</p> <p>19 MR. DE LA CERDA: Okay. So I'm going to</p> <p>20 mark this book as Exhibit 4 and then if we can</p> <p>21 just get a copy of chapter 7, just chapter 7,</p> <p>22 then the book can be returned.</p> <p>23</p> <p>24</p>

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<p>1 (Plaintiff's Exhibit No. 4 was marked for</p> <p>2 identification.)</p> <p>3 Q. (By Mr. De La Cerda) You've also brought</p> <p>4 a book entitled "Introductory Biomechanics From</p> <p>5 Cells to Organisms." The author is -- or authors</p> <p>6 are C. Ross Ethier, E-t-h-i-e-r, and Craig A.</p> <p>7 Simmons. It looks like this is published by</p> <p>8 Cambridge University Press.</p> <p>9 Are there any chapters or passages within</p> <p>10 this book --</p> <p>11 A. Yes.</p> <p>12 Q. -- that supports your opinions?</p> <p>13 A. Chapter 9.</p> <p>14 Q. Okay. Great. I'll mark this book,</p> <p>15 "Introductory Biomechanics," as Exhibit 5 and then</p> <p>16 we'll just get a copy of that particular chapter you</p> <p>17 referenced, chapter 9.</p> <p>18 (Plaintiff's Exhibit No. 5 was marked for</p> <p>19 identification.)</p> <p>20 MR. DE LA CERDA: Another book you brought</p> <p>21 is called "Biomaterials and Biomedical</p> <p>22 Engineering" published by Trans, T-r-a-n-s, Tech,</p> <p>23 T-e-c-h, Publications. This one is edited by W.</p> <p>24 Ahmed, A-h-m-e-d, N. Ali, A-l-i, and A. Öchsner.</p>	<p>1 on his materials list. For some reason these</p> <p>2 don't have page numbers, but it's under "other</p> <p>3 materials."</p> <p>4 MR. DE LA CERDA: Okay.</p> <p>5 MR. SNELL: I put a check next to it.</p> <p>6 MR. DE LA CERDA: Okay. Great. All right.</p> <p>7 Q. (By Mr. De La Cerda) Now, the last bit of</p> <p>8 materials that you brought with you are various</p> <p>9 thumb drives. What are these thumb drives?</p> <p>10 A. These are the thumb drives that have the</p> <p>11 articles that you see in these binders.</p> <p>12 Q. Oh, I see. Okay. So actually, it would be</p> <p>13 nice to go ahead and mark these. So we have four</p> <p>14 different thumb drives. Each of these thumb drives is</p> <p>15 actually labeled with a product, as well. So there is</p> <p>16 Sepulveda TVT - TVT-O, Sepulveda TVT-S, Sepulveda</p> <p>17 Prolift, and then there's another Sepulveda TVT-S, I</p> <p>18 don't know if that's just a repeat, but I'll mark each</p> <p>19 of these with its own sticker. We're on 6.</p> <p>20 So I'm marking as Exhibit 7 to your</p> <p>21 deposition the thumb drive that has Sepulveda TVT and</p> <p>22 TVT-O and this thumb drive contains reliance materials</p> <p>23 and materials cited in your report; correct?</p> <p>24 A. Yes.</p>
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<p>1 It's O-umlaut-c-h-s-n-e-r.</p> <p>2 And I'm marking this book as Exhibit 6.</p> <p>3 (Plaintiff's Exhibit No. 6 was marked for</p> <p>4 identification.)</p> <p>5 Q. (By Mr. De La Cerda) Are there any</p> <p>6 chapters or passages in that book that you rely on?</p> <p>7 A. Yes.</p> <p>8 Q. What are they?</p> <p>9 A. Chapter 12.</p> <p>10 Q. Okay. Thank you. And then we'll get a copy</p> <p>11 of that and return the original book to you.</p> <p>12 Okay. Now, you've also -- the other</p> <p>13 material other than the case-specific materials, the</p> <p>14 other material -- materials you've brought with you</p> <p>15 have all been cited either in your report or in your</p> <p>16 Reliance List; correct?</p> <p>17 A. That's correct.</p> <p>18 Q. Okay. Great. Now the last thing I'm going</p> <p>19 to do --</p> <p>20 MR. SNELL: Peter, one thing --</p> <p>21 MR. DE LA CERDA: Yes.</p> <p>22 MR. SNELL: -- for clarification. I had</p> <p>23 mentioned I thought the ACOG physician statement</p> <p>24 from 2011 on transvaginal POP mesh was in. It's</p>	<p>1 (Plaintiff's Exhibit No. 7 was marked for</p> <p>2 identification.)</p> <p>3 Q. (By Mr. De La Cerda) Then I'm marking as</p> <p>4 Exhibit 8, Sepulveda TVT-S, and these are also</p> <p>5 documents referenced in your Reliance List and your</p> <p>6 report relating to TVT-S; correct?</p> <p>7 A. Yes.</p> <p>8 (Plaintiff's Exhibit No. 8 was marked for</p> <p>9 identification.)</p> <p>10 Q. (By Mr. De La Cerda) Then I'm marking as</p> <p>11 Exhibit 9 to your deposition the thumb drive that</p> <p>12 has -- that's marked Sepulveda Prolift, and these</p> <p>13 are materials referenced in your Reliance List and</p> <p>14 your report for Prolift; correct?</p> <p>15 A. Yes.</p> <p>16 (Plaintiff's Exhibit No. 9 was marked for</p> <p>17 identification.)</p> <p>18 MR. DE LA CERDA: Do you know why there is a</p> <p>19 second TVT-S one?</p> <p>20 MR. SNELL: I have no idea.</p> <p>21 MR. DE LA CERDA: I'll just mark it as</p> <p>22 another one.</p> <p>23 MR. SNELL: Somebody might have just made</p> <p>24 two copies. I can open it up and look at it real</p>

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<p style="text-align: right;">Page 50</p> <p>1 quick.</p> <p>2 MR. DE LA CERDA: I'll just mark it.</p> <p>3 Then I'm also marking as Exhibit 10 to your</p> <p>4 deposition a second thumb drive labeled</p> <p>5 "Sepulveda TVT-S," which I assume is also</p> <p>6 reliance materials and documents referenced</p> <p>7 within your report; correct?</p> <p>8 A. Yes.</p> <p>9 (Plaintiff's Exhibit No. 10 was marked for</p> <p>10 identification.)</p> <p>11 MR. DE LA CERDA: Case-specific, they can</p> <p>12 deal with that.</p> <p>13 THE WITNESS: I need to -- to -- I did not</p> <p>14 remember seeing the Bianchi-Ferraro --</p> <p>15 THE COURT REPORTER: I'm sorry, the --</p> <p>16 THE WITNESS: I do not remember seeing the</p> <p>17 Bianchi-Ferraro paper on TVT-Secur and TVT-O.</p> <p>18 MR. SNELL: Is it in this pile?</p> <p>19 THE WITNESS: I want to double-check that</p> <p>20 because I --</p> <p>21 MR. SNELL: Bianchi-Ferraro?</p> <p>22 THE WITNESS: Bianchi-Ferraro, which I</p> <p>23 referred to in the Garcia deposition.</p> <p>24 MR. SNELL: Okay. This is other literature.</p>	<p style="text-align: right;">Page 52</p> <p>1 Exhibit 11 contains additional medical literature that</p> <p>2 you're relying on for your opinions; is that right?</p> <p>3 A. Yes.</p> <p>4 Q. Okay. We'll just leave it at that and then,</p> <p>5 of course, if you need to refer to any of it during</p> <p>6 your deposition --</p> <p>7 A. And this is the paper that I was just</p> <p>8 referring about the Bianchi-Ferraro on TVT-O and</p> <p>9 TVT-S.</p> <p>10 MR. DE LA CERDA: Okay. So I'll mark this</p> <p>11 one separately as Exhibit 12.</p> <p>12 MR. SNELL: Is that one in your report, do</p> <p>13 you know?</p> <p>14 THE WITNESS: No, but I refer to it on the</p> <p>15 Garcia deposition.</p> <p>16 (Plaintiff's Exhibit No. 12 was marked for</p> <p>17 identification.)</p> <p>18 MR. DE LA CERDA: For purposes of the</p> <p>19 record, Exhibit 12 is a article entitled</p> <p>20 "Randomized controlled trial comparing TVT-O and</p> <p>21 TVT-S for the treatment of stress urinary</p> <p>22 incontinence: 2-year results."</p> <p>23 Is it okay if I clip --</p> <p>24 A. Yes.</p>
<p style="text-align: right;">Page 51</p> <p>1 You want to give that to him. That's additional.</p> <p>2 THE WITNESS: Additional.</p> <p>3 MR. DE LA CERDA: Oh, okay. All right. I'm</p> <p>4 also marking as Exhibit 11 medical literature</p> <p>5 that you've handed to me.</p> <p>6 (Plaintiff's Exhibit No. 11 was marked for</p> <p>7 identification.)</p> <p>8 Q (By Mr. De La Cerda) What is this medical</p> <p>9 literature?</p> <p>10 A. That is -- this is medical literature about</p> <p>11 the -- one case report of clear cell carcinoma of the</p> <p>12 vagina and there's -- in a patient that has had a</p> <p>13 midurethral sling. This is the response to that</p> <p>14 article.</p> <p>15 Q. (By Mr. De La Cerda) Okay. So this is</p> <p>16 all within Exhibit 11. So the second article within</p> <p>17 Exhibit 11 is?</p> <p>18 A. The response to this article.</p> <p>19 Q. Okay. And the third article within</p> <p>20 Exhibit 11?</p> <p>21 A. This is vaginal -- these are different</p> <p>22 papers, but they're not directly related to this one.</p> <p>23 Q. That's okay. So these are all -- I guess</p> <p>24 just to make sure just for purposes of the record,</p>	<p style="text-align: right;">Page 53</p> <p>1 Q. (By Mr. De La Cerda) Just for now, and</p> <p>2 then if you need to look at them, of course.</p> <p>3 A. And I gave you a copy of my CV --</p> <p>4 Q. Yes.</p> <p>5 A. -- without my home address.</p> <p>6 Q. Okay. I've got one here and if you like, I</p> <p>7 can use this one for the record.</p> <p>8 A. Yes, I just made it available to you in</p> <p>9 case ...</p> <p>10 MR. SNELL: Is that the same thing?</p> <p>11 THE WITNESS: Yes, that's the one. The</p> <p>12 Bianchi-Ferraro has been referred already on</p> <p>13 this.</p> <p>14 MR. SNELL: Footnote 117.</p> <p>15 Q. (By Mr. De La Cerda) Okay. What I'm</p> <p>16 going to do is I'm going to mark as Exhibit 13 to</p> <p>17 your deposition your CV.</p> <p>18 (Plaintiff's Exhibit No. 13 was marked for</p> <p>19 identification.)</p> <p>20 Q (By Mr. De La Cerda) So I'm marking as</p> <p>21 Exhibit 13, that's your -- is that your current</p> <p>22 curriculum vitae?</p> <p>23 A. Yes.</p> <p>24 Q. And is that, to the best of your knowledge,</p>

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<p style="text-align: right;">Page 54</p> <p>1 current?</p> <p>2 A. It is -- it is current.</p> <p>3 Q. Okay. Anything else -- anything on it that</p> <p>4 you know of that needs to be updated, corrected,</p> <p>5 edited, anything like that?</p> <p>6 A. On my report that I'm the principal</p> <p>7 investigator at the Fibroid Registry research project,</p> <p>8 that project was completed and closed.</p> <p>9 Q. Okay. And is that the only thing on your CV</p> <p>10 that you know of that would need to be corrected?</p> <p>11 A. It was the only research project that was</p> <p>12 open.</p> <p>13 (Plaintiff's Exhibit No. 14 was marked for</p> <p>14 identification.)</p> <p>15 Q. (By Mr. De La Cerda) Okay. I'm also</p> <p>16 marking as Exhibit 14 to your deposition your</p> <p>17 Reliance List for the general report.</p> <p>18 This is what I've received as your Reliance</p> <p>19 List. Does that appear to be a true and correct copy</p> <p>20 of it?</p> <p>21 MR. SNELL: Is this Exhibit 14?</p> <p>22 MR. DE LA CERDA: Yeah.</p> <p>23 A. I don't see any discrepancies overall in</p> <p>24 this list from what I have here.</p>	<p style="text-align: right;">Page 56</p> <p>1 (Thereupon, a recess was taken from</p> <p>2 9:24 a.m. until 9:26 a.m., after which the</p> <p>3 following proceedings were held:)</p> <p>4 Q. (By Mr. De La Cerda) All right. Doctor,</p> <p>5 we're back on the record.</p> <p>6 When -- when was it that you were first</p> <p>7 contacted regarding the general opinions that you have</p> <p>8 as to these products that we're here today for?</p> <p>9 A. For -- for the -- for the MDL, around</p> <p>10 September. We spoke around September.</p> <p>11 Q. September --</p> <p>12 A. Last year.</p> <p>13 Q. -- of last year, 2015?</p> <p>14 A. Yes.</p> <p>15 Q. And do you recall who you talked to first?</p> <p>16 A. I -- I spoke to Burt.</p> <p>17 Q. Okay. And was the topic discussed that you</p> <p>18 would be providing general opinions as to these</p> <p>19 specific products: TVT, TVT-O, Proxima, Prolift and</p> <p>20 Gynemesh?</p> <p>21 A. That's correct.</p> <p>22 Q. And what was the scope of your assignment</p> <p>23 for this particular -- for your opinions in this case,</p> <p>24 to your understanding?</p>
<p style="text-align: right;">Page 55</p> <p>1 Q. (By Mr. De La Cerda) Okay. Great. Now</p> <p>2 I'm going to show you what I've marked as Exhibit 15</p> <p>3 to your deposition.</p> <p>4 (Plaintiff's Exhibit No. 15 was marked for</p> <p>5 identification.)</p> <p>6 Q. (By Mr. De La Cerda) Does this appear to</p> <p>7 be a true and correct copy of your expert report,</p> <p>8 your general expert report, on Gynemesh, Prolift and</p> <p>9 Proxima?</p> <p>10 A. This is accurate and correct.</p> <p>11 (Plaintiff's Exhibit No. 16 was marked for</p> <p>12 identification.)</p> <p>13 Q. (By Mr. De La Cerda) Okay. And now I'm</p> <p>14 showing you what I've marked as Exhibit 16 to your</p> <p>15 deposition. Does this appear to be a true and</p> <p>16 correct copy of your general expert report on TVT</p> <p>17 and TVT-O?</p> <p>18 A. It is a correct copy.</p> <p>19 MR. DE LA CERDA: We've been going now for</p> <p>20 about an hour. Are you okay to continue or do</p> <p>21 you want to take a break?</p> <p>22 THE WITNESS: Let's take a bladder break and</p> <p>23 we'll come back in five.</p> <p>24 MR. DE LA CERDA: Sounds good.</p>	<p style="text-align: right;">Page 57</p> <p>1 A. Yes, I understand the scope is to -- to</p> <p>2 review the literature and -- and go over things that I</p> <p>3 have read for -- throughout the years.</p> <p>4 Q. Were there certain things that you were to</p> <p>5 focus on within the context of your opinions?</p> <p>6 A. The --</p> <p>7 THE COURT REPORTER: I'm sorry, did you --</p> <p>8 MR. SNELL: Objection, form. I just say</p> <p>9 "form," but that means objection, form. I try to</p> <p>10 cut down your typing on the record.</p> <p>11 A. The randomized controlled trials concentrate</p> <p>12 in the evidence.</p> <p>13 Q. (By Mr. De La Cerda) What about internal</p> <p>14 documents, was there any focus that you were to</p> <p>15 place on the substance or the significance of</p> <p>16 Ethicon's internal documents in forming your</p> <p>17 opinions?</p> <p>18 A. No. It's -- I have received -- just to be</p> <p>19 accurate in my response, I received, probably a year</p> <p>20 ago, internal documents, but not as part of this.</p> <p>21 Q. Okay. So your focus really was and your</p> <p>22 opinions here was to provide those opinions based on</p> <p>23 literature as opposed to what was found in the</p> <p>24 internal documents; is that fair?</p>

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<p>1 MR. SNELL: Form.</p> <p>2 A. Based on the -- on the evidence, on the</p> <p>3 scientific evidence.</p> <p>4 Q. (By Mr. De La Cerda) As opposed to the</p> <p>5 internal documents; right?</p> <p>6 A. The internal documents are not -- are not</p> <p>7 included on -- on this review or -- because it's a</p> <p>8 scientific review.</p> <p>9 Q. I guess you haven't completed all -- well,</p> <p>10 let me just ask.</p> <p>11 Have you completed all of your work on this</p> <p>12 case?</p> <p>13 A. Yes. So far from my Reliance List and this</p> <p>14 is -- this is the product.</p> <p>15 Q. Do you currently have any further work</p> <p>16 planned?</p> <p>17 A. As -- as information may be required,</p> <p>18 I'll -- I'll review the papers, I'll review scientific</p> <p>19 literature, and everything that is coming up.</p> <p>20 Q. So -- but as far as anything specific</p> <p>21 planned, is there any additional -- is there any</p> <p>22 additional task that you have planned? Other than,</p> <p>23 you know, tomorrow we have depositions for the</p> <p>24 case-specific, but other than the depositions coming</p>	<p>1 A. I can make copies again of it, but I did</p> <p>2 prepare your invoices. My invoices to -- I put it in</p> <p>3 a folder, they were neatly organized, the hours. I --</p> <p>4 I just cannot find it, honestly cannot find it.</p> <p>5 Q. (By Mr. De La Cerda) Okay. So what we'll</p> <p>6 do is when you do find it, you'll agree to provide</p> <p>7 that to us?</p> <p>8 A. Absolutely.</p> <p>9 Q. Okay. And so --</p> <p>10 MR. SNELL: Why don't we save an exhibit</p> <p>11 number on the record, and I'll produce that, but</p> <p>12 I think he probably has a good idea as to how</p> <p>13 many hours he spent.</p> <p>14 MR. DE LA CERDA: Okay. So what I'm going</p> <p>15 to do is, I'm reserving Exhibit 17 for the</p> <p>16 invoices that Dr. Sepulveda has prepared</p> <p>17 reflecting his work and his opinions for this</p> <p>18 case.</p> <p>19 (Plaintiff's Exhibit No. 17 was marked for</p> <p>20 identification.)</p> <p>21 Q. (By Mr. De La Cerda) First of all, do you</p> <p>22 have an idea of approximately how many hours you've</p> <p>23 spent preparing your opinions?</p> <p>24 A. It's -- an approximate is about 120 hours.</p>
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<p>1 up tomorrow, are there any specific tasks that you</p> <p>2 have planned relating to your opinions in this case?</p> <p>3 A. No, this is -- this is my -- my product.</p> <p>4 MR. SNELL: I'll make a note for the record.</p> <p>5 As plaintiff's experts' depositions are coming</p> <p>6 in, I know there are still depositions going on</p> <p>7 today, tomorrow, we'll send those to him, and if</p> <p>8 he has commentary or his opinions are changed,</p> <p>9 then, obviously, I'll let you know.</p> <p>10 Q. (By Mr. De La Cerda) How much have you</p> <p>11 billed thus far for your general opinions involving</p> <p>12 TVT, TVT-O, Proxima, Prolift and Gynemesh?</p> <p>13 A. I have -- I have copies of the invoices that</p> <p>14 I have submitted.</p> <p>15 Is it okay if he has other -- other hours</p> <p>16 from another case, or should I just say the number of</p> <p>17 hours?</p> <p>18 MR. SNELL: Let me see what you're talking</p> <p>19 about. The invoices -- let me look at them real</p> <p>20 quick.</p> <p>21 MR. DE LA CERDA: Do you want to go off the</p> <p>22 record for a second? Let's go off the record.</p> <p>23 (Discussion held off the record.)</p> <p>24 (Mr. Sparks entered the room.)</p>	<p>1 Q. And your report mentions that you bill at</p> <p>2 \$500 an hour; right?</p> <p>3 A. Yes.</p> <p>4 Q. And so was it -- was that rate the same for</p> <p>5 all 120 hours that you performed --</p> <p>6 A. Yes.</p> <p>7 Q. And was -- do you know whether your invoice,</p> <p>8 did it break down the tasks that you were performing,</p> <p>9 did it break it down by product?</p> <p>10 A. No, it's all MDL.</p> <p>11 Q. Okay. Was it broken down by, for example,</p> <p>12 reviewing documents, meeting -- meetings with defense</p> <p>13 counsel, deposition time? Was it broken down in any</p> <p>14 way like that?</p> <p>15 A. No, it's just for MDL, all the time that</p> <p>16 I've spent in putting -- putting together -- putting</p> <p>17 the reports together, putting -- for all the different</p> <p>18 products all into one MDL.</p> <p>19 Q. Okay. So one block bill of 120 hours --</p> <p>20 A. Right.</p> <p>21 Q. -- approximately?</p> <p>22 A. That's correct. Around -- approximately.</p> <p>23 Q. Okay. Now, the types of tasks you would</p> <p>24 perform in developing your opinions, what did those</p>

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<p>1 include?</p> <p>2 A. I have to write the report, I have to</p> <p>3 proofread -- proofread it, and I update it with the --</p> <p>4 with the Reliance List. I -- I do research and</p> <p>5 whatever papers I -- I find that are relevant, I just</p> <p>6 submit it and it gets added to the Reliance List.</p> <p>7 Q. Okay.</p> <p>8 A. I also -- I review the case specifics and</p> <p>9 that included seven -- seven cases in which -- in</p> <p>10 which depositions and medical records and summaries</p> <p>11 were reviewed.</p> <p>12 Q. Okay.</p> <p>13 A. And then the time, getting together, getting</p> <p>14 prepared for this.</p> <p>15 Q. Anything else that you can think of?</p> <p>16 A. That would be at a later time because we got</p> <p>17 ready yesterday and the time today.</p> <p>18 Q. Let's talk a little about what you just</p> <p>19 mentioned. Does the 120 -- approximately 120 hours</p> <p>20 that you mentioned, does that include all of your work</p> <p>21 for the case-specific?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. Do you know approximately how much</p> <p>24 you spent -- how much time you spent as to each</p>	<p>1 A. Yes.</p> <p>2 Q. Anybody else?</p> <p>3 A. No.</p> <p>4 Q. In your deposition preparation, you reviewed</p> <p>5 documents; is that right?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. Are those the documents that we have</p> <p>8 here that we've marked today?</p> <p>9 A. Yes.</p> <p>10 Q. Okay.</p> <p>11 A. And -- yeah, all this has been marked.</p> <p>12 Q. Do you have any rough estimate of how much</p> <p>13 more you anticipate billing before trial?</p> <p>14 A. I -- I don't know when it's going to trial.</p> <p>15 It's -- as they -- as they require, I just -- I'll</p> <p>16 just review.</p> <p>17 Q. Okay. Have you ever rendered an opinion in</p> <p>18 litigation that was adverse to Johnson & Johnson or</p> <p>19 Ethicon, Inc.?</p> <p>20 A. No.</p> <p>21 Q. Did you take any notes while you were doing</p> <p>22 your preparation for your opinions?</p> <p>23 A. I -- I'm a better highlighter than note</p> <p>24 taker.</p>
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<p>1 case-specific report that you prepared?</p> <p>2 A. I -- I probably spend about, just -- just a</p> <p>3 rough, rough estimate, it's ten hours per each one,</p> <p>4 each one of them.</p> <p>5 Q. And do you know how many case-specific</p> <p>6 reports you prepared?</p> <p>7 A. Seven.</p> <p>8 Q. Seven. Okay. I know these are rough</p> <p>9 numbers here, but so seven case-specific reports at</p> <p>10 about ten hours a piece, it's about 70 hours. So the</p> <p>11 balance, the rest of that, would that be dedicated</p> <p>12 towards your general opinions as to the products</p> <p>13 involved here?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. And you mentioned preparation for</p> <p>16 your deposition. When is it that you prepared for</p> <p>17 your deposition today?</p> <p>18 A. Yesterday.</p> <p>19 Q. And how long did you prepare?</p> <p>20 A. We -- we spend eight, ten hours.</p> <p>21 Q. And that's eight to ten hours that you spent</p> <p>22 with Burt Snell?</p> <p>23 A. Yes.</p> <p>24 Q. Counsel for Ethicon; right?</p>	<p>1 Q. Okay. I can never read my own notes, so I</p> <p>2 don't -- I don't even take notes.</p> <p>3 Okay. So you don't have any handwritten</p> <p>4 notes regarding your opinions; is that right?</p> <p>5 A. No, not on this.</p> <p>6 Q. You mentioned the Reliance List. Was the</p> <p>7 Reliance List originally prepared and provided to you</p> <p>8 by Ethicon counsel?</p> <p>9 A. It -- it was given by counsel, but I can</p> <p>10 tell you that most of that Reliance List is trials</p> <p>11 that are relevant enough that I have read it over</p> <p>12 time.</p> <p>13 Q. Okay. So then as you performed your own</p> <p>14 research and found additional articles, you would then</p> <p>15 submit them to Ethicon's counsel and then they would</p> <p>16 get added to the Reliance List; is that right?</p> <p>17 A. Right. That's -- whatever I want to add up,</p> <p>18 I just submit.</p> <p>19 Q. And that Reliance List is exhaustive other</p> <p>20 than a few of the articles that we've identified</p> <p>21 today, is that right, that have been marked?</p> <p>22 A. Right, that's -- this is what includes it.</p> <p>23 Q. Does your Reliance --</p> <p>24 MR. SNELL: Could I make -- let me just make</p>

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<p>1 a note on the record. He did bring another thumb</p> <p>2 drive with a lot of Ethicon documents and</p> <p>3 materials that he had in his possession and,</p> <p>4 obviously, those would go and make up part and</p> <p>5 parcel of his knowledge base as well.</p> <p>6 MR. DE LA CERDA: I'm glad you brought that</p> <p>7 up because I forgot to mark this thumb drive.</p> <p>8 THE WITNESS: Can you just take a look</p> <p>9 because I want to make sure I brought the right</p> <p>10 thumb drive.</p> <p>11 MR. SNELL: Okay.</p> <p>12 THE WITNESS: I just dump it and I really</p> <p>13 never review it.</p> <p>14 I'm seeing one of the slides have the name</p> <p>15 of a patient.</p> <p>16 MR. SNELL: How do we deal with that?</p> <p>17 because it looks like an image.</p> <p>18 THE WITNESS: It's an image, yeah, it has a</p> <p>19 name of a patient.</p> <p>20 MR. SNELL: It has to be redacted.</p> <p>21 THE WITNESS: Yeah.</p> <p>22 MR. SNELL: Why don't we take it off the</p> <p>23 thumb drive and we can figure out how to redact</p> <p>24 it.</p>	<p>1 presentation on Gynemesh, and it has the surgical</p> <p>2 videos, and it has pictures of surgery that I have</p> <p>3 included in those presentations.</p> <p>4 MR. SNELL: Did you mention this product?</p> <p>5 THE WITNESS: TVT-Secur.</p> <p>6 Q. (By Mr. De La Cerda) And, apparently,</p> <p>7 there are patient-identifying information on that</p> <p>8 thumb drive and so that information is going to be</p> <p>9 redacted and then the thumb drive will be provided</p> <p>10 at a later date; correct?</p> <p>11 A. There is one slide that has the patient ID.</p> <p>12 MR. SNELL: What I was going to do is take</p> <p>13 the file titled "Pillowing" with the</p> <p>14 patient-protected information off the thumb</p> <p>15 drive, put it on my local computer, and figure</p> <p>16 out some time today if this law firm can redact</p> <p>17 that.</p> <p>18 MR. DE LA CERDA: That would be perfect.</p> <p>19 MR. SNELL: But you'll have -- I mean, but</p> <p>20 we'll mark the thumb drive, because I want a copy</p> <p>21 of it, too.</p> <p>22 MR. DE LA CERDA: Okay.</p> <p>23 MR. SNELL: I'm just looking for -- is that</p> <p>24 your data?</p>
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<p>1 So Peter, just for your reference, we're</p> <p>2 looking at the thumb drive Dr. Sepulveda brought.</p> <p>3 There is a PowerPoint titled "Pillowing,</p> <p>4 P-i-l-l-o-w-i-n-g, .ppxt, and it's got patient</p> <p>5 identification information, so we'll take that</p> <p>6 off the thumb drive and figure out how to redact</p> <p>7 that. It looks like it's images. I can't even</p> <p>8 read the name, but obviously once you open up the</p> <p>9 file in realtime you can see it.</p> <p>10 MR. DE LA CERDA: Okay. So for purposes of</p> <p>11 the record, we're going to reserve --</p> <p>12 Did we already reserve 17?</p> <p>13 THE COURT REPORTER: Yes, for --</p> <p>14 MR. SNELL: I think 17 was invoices.</p> <p>15 MR. DE LA CERDA: Okay. So for purposes of</p> <p>16 the record, we're going to reserve Exhibit No. 18</p> <p>17 for a thumb drive that Dr. Sepulveda has brought</p> <p>18 here today.</p> <p>19 Q (By Mr. De La Cerda) And, for the record,</p> <p>20 Dr. Sepulveda, can you tell us, generally speaking,</p> <p>21 what is on the thumb drive that will be marked as</p> <p>22 Exhibit 18?</p> <p>23 A. It -- it has the presentations that I have</p> <p>24 used for Prolift throughout the years, and it has the</p>	<p>1 THE WITNESS: Yes, that's my own data.</p> <p>2 MR. SNELL: Tell him about that.</p> <p>3 A. I also included data of my own</p> <p>4 complications.</p> <p>5 Q. (By Mr. De La Cerda) Let's discuss them.</p> <p>6 Actually, you know what, we'll come to that shortly.</p> <p>7 MR. SNELL: Is that the same as the earlier</p> <p>8 stuff without the patient identifying --</p> <p>9 THE WITNESS: No, that's -- I put all the</p> <p>10 files that have to do with it, so I had the files</p> <p>11 that I use to prepare the presentation, and I</p> <p>12 have the actual file slides with the</p> <p>13 presentation.</p> <p>14 MR. SNELL: Did you mention this product?</p> <p>15 THE WITNESS: That's TVT-Secur.</p> <p>16 MR. SNELL: This one?</p> <p>17 THE WITNESS: And there's another</p> <p>18 presentation on TVT-O.</p> <p>19 MR. SNELL: Okay. Let me pull that one off.</p> <p>20 Q. (By Mr. De La Cerda) Okay. And we'll</p> <p>21 come back to the data on your own complications,</p> <p>22 too. We'll discuss that in a moment.</p> <p>23 Okay. Directing your attention back to</p> <p>24 Exhibit 16 -- oh, wait. Is this report -- in</p>

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<p style="text-align: right;">Page 70</p> <p>1 Exhibit 16 is your general report on TVT and TVT-O; 2 correct? 3 A. That's correct. 4 Q. Is this report a complete statement of all 5 general opinions that you'll express as to the TVT and 6 the TVT-O and the reasons for those opinions? 7 A. That report includes that, up to -- up to 8 today. 9 Q. So up to today, that report is a complete 10 statement of all general opinions you'll express as to 11 the TVT and TVT-O and the reasons for those opinions; 12 correct? 13 MR. SNELL: Form. 14 Go ahead. 15 A. That's correct. 16 Q. (By Mr. De La Cerda) Does this report, 17 your Reliance List, and the materials you've brought 18 today include all facts or data considered by you as 19 of today in forming your general opinions about the 20 TVT and the TVT-O? 21 A. Yes. 22 MR. SNELL: I took the one file off so you 23 can go ahead and mark that. 24 MR. DE LA CERDA: All right. So I am, for</p>	<p style="text-align: right;">Page 72</p> <p>1 Q. And do you currently perform surgeries to 2 correct stress urinary incontinence? 3 A. Yes. 4 Q. Now let's focus over the last ten years. 5 Over the last ten years, what surgeries have 6 you performed to correct stress urinary incontinence? 7 A. I have performed Burch procedures, TVT, 8 retropubic, and transobturator inside-out. 9 Q. Is that TVT-O? 10 A. That's correct, that's TVT-O. 11 And TVT-Secur, TVT-ABBREVO. 12 Q. Okay. Any others that you can recall 13 sitting here today? 14 A. I -- I recall doing 50 outside-in slings. 15 Q. Fifty outside-in slings. 16 A. Slings. 17 Q. Okay. Do you recall the brand of those? 18 A. That was from AMS. 19 Q. AMS. Is that the Monarc? 20 A. Monarc. 21 Q. You mentioned that you performed Burch as a 22 surgery to correct stress urinary incontinence. What 23 to you would be an indication to perform a Burch as 24 opposed to a synthetic midurethral sling?</p>
<p style="text-align: right;">Page 71</p> <p>1 the record, marking the thumb drive that we've 2 just discussed that Dr. Sepulveda brought as 3 Exhibit 18. 4 (Plaintiff's Exhibit No. 18 was marked for 5 identification.) 6 Q. (By Mr. De La Cerda) Okay. Now, Doctor, 7 directing your attention to Exhibit 15 and that's 8 your report on the Gynemesh, Prolift and Prosima; 9 correct? 10 A. Yes. 11 Q. Now, is this report a complete statement of 12 all general opinions you will express as to the 13 Gynemesh, Prolift, and Prosima and the reasons for 14 those opinions as of today? 15 A. Yes. 16 Q. And does this report, your Reliance List, 17 and the materials you brought today include all facts 18 or data considered by you in forming your general 19 opinions about the TVT and the TVT-O as of today? 20 A. Yes. 21 Q. Okay. Let's talk a little bit about your 22 practice. Where do you currently have privileges? 23 A. At South Miami Hospital, Baptist Hospital, 24 and South Miami Medical Arts Surgery Center.</p>	<p style="text-align: right;">Page 73</p> <p>1 A. I perform Burches rarely and I cannot -- I 2 cannot really remember off my head my last Burch. 3 Q. Why do you perform them rarely? 4 A. Because midurethral synthetic slings work 5 very well. 6 Q. Performing a synthetic midurethral sling, 7 it's a quicker procedure than a Burch; right? 8 A. It's just more than -- than quicker. It 9 performs -- short term and a long term, it performs 10 better than a Burch and it's -- that has been -- has 11 been my experience and that's what's supported by 12 data. 13 Q. Okay. So -- but are there any indications 14 to you -- when a patient comes into your office and 15 you're going to perform a surgery to correct the 16 stress urinary incontinence, what indications do you 17 say, I'm going to perform a Burch instead of a 18 synthetic midurethral sling? 19 A. My first option is a synthetic midurethral 20 sling and I counsel the patients on it. There may -- 21 I may have a patient that may say I want a Burch for 22 one or other reason. 23 Q. Okay. So it's the patient making the 24 decision that they prefer a Burch over a synthetic</p>

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<p>1 midurethral sling as opposed to you recommending the</p> <p>2 Burch as the first option?</p> <p>3 A. My patients are -- I have a well-educated</p> <p>4 practice and they -- they actually may -- may bring</p> <p>5 great questions about one or the other. My experience</p> <p>6 is that they will follow my -- my recommendations.</p> <p>7 Q. Right. Do you recall any instance where</p> <p>8 you've recommended a Burch over a synthetic</p> <p>9 midurethral sling?</p> <p>10 A. There -- there was a time about when TVT</p> <p>11 came in and for one or two years that we spoke in</p> <p>12 those terms, but once randomized controlled trials</p> <p>13 came in, it was -- I tell them that that's</p> <p>14 basically -- is the best evidence that I have.</p> <p>15 Q. Your understanding was that at least at one</p> <p>16 time the Burch was the gold standard for correcting</p> <p>17 stress urinary incontinence surgically; correct?</p> <p>18 A. I -- I'm going to take exception to the</p> <p>19 "gold standard" term, but there was a time in which</p> <p>20 the Burch was the correct clinical -- clinical</p> <p>21 practice.</p> <p>22 Q. Would you use the gold standard term to</p> <p>23 describe a synthetic midurethral sling?</p> <p>24 A. I -- I just try to shy away from "gold</p>	<p>1 A. It took very little for her to leak.</p> <p>2 Q. Okay. And so why would it be that you would</p> <p>3 use a biologic sling under those circumstances?</p> <p>4 A. I use actually her own fascia and it -- it</p> <p>5 was -- we didn't have anything -- anything -- we have</p> <p>6 things that were synthetic but that were not</p> <p>7 well-studied at that time.</p> <p>8 Q. So this would have been, I assume, in either</p> <p>9 the late '90s or early 2000s?</p> <p>10 A. That's a wide range, yes.</p> <p>11 Q. Okay. You mentioned TVT Retropubic, TVT-O,</p> <p>12 TVT-S, and TVT-ABBREVO that you performed in the last</p> <p>13 ten years.</p> <p>14 Do you know approximately how many of each</p> <p>15 of those you performed?</p> <p>16 A. I -- I counted about -- at one time it was</p> <p>17 about 300 slings a year.</p> <p>18 Q. Okay. And do you know what the breakdown</p> <p>19 was of those 300 per year as to the TVT Retropubic,</p> <p>20 TVT-O, TVT-S, and TVT-ABBREVO?</p> <p>21 A. It was an evolution from TVT Retropubic to</p> <p>22 TVT-O and to TVT-Secur and then ABBREVO.</p> <p>23 Q. Okay. So over -- over time, you might --</p> <p>24 you know, you started with a TVT Retropubic, then</p>
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<p>1 standard." I think that clinically, it's -- the</p> <p>2 current clinical standard is probably a better -- a</p> <p>3 better term.</p> <p>4 Q. So a current clinical standard is a better</p> <p>5 term to use than the term "gold standard"; right?</p> <p>6 A. I -- I agree.</p> <p>7 Q. Did you -- in the last ten years, have you</p> <p>8 ever used slings using biologic materials?</p> <p>9 A. I -- I don't know if it's within the last</p> <p>10 ten years, but I -- I have used slings using</p> <p>11 autologous, I have done slings using dermis cadaver</p> <p>12 material. I may have used them one time posing, but</p> <p>13 this is so -- so remote that -- that I cannot tell you</p> <p>14 how many or which brand did I use.</p> <p>15 Q. Do you remember any reasons why you would</p> <p>16 have used those biologic slings?</p> <p>17 A. If I had some- -- if I had someone that --</p> <p>18 that was -- the person that comes to mind is my -- the</p> <p>19 last pubovaginal sling and it was a smoker with --</p> <p>20 with bad pressures in the urethra and I used the</p> <p>21 pubovaginal sling in that patient at that time.</p> <p>22 Q. What do you mean by "bad pressures"?</p> <p>23 A. Very, very low pressures in the urethra.</p> <p>24 Q. Okay.</p>	<p>1 you -- then you preferred the TVT-O, so you would</p> <p>2 switch to that; is that right?</p> <p>3 A. Yes.</p> <p>4 Q. And then you would prefer the TVT-S and you</p> <p>5 would switch to that?</p> <p>6 A. Yes.</p> <p>7 Q. And then later you preferred the TVT-ABBREVO</p> <p>8 and switched to that; is that right?</p> <p>9 A. Right.</p> <p>10 Q. Do you still perform TVT-Os, though, or do</p> <p>11 you just kind of stick with the TVT-ABBREVO?</p> <p>12 A. I do it at the surgery center so we choose</p> <p>13 one. And since I do most of the slings, and I'm the</p> <p>14 medical director for the surgery center, I decide I'm</p> <p>15 going to use this or that one. We still have TVT-O on</p> <p>16 the shelf, but we -- we use TVT -- TVT-ABBREVO.</p> <p>17 Q. Okay. Why would you prefer a TVT-ABBREVO</p> <p>18 over a TVT-O?</p> <p>19 MR. SNELL: Form.</p> <p>20 A. I have not found a scientific -- a</p> <p>21 scientific reason for it except for the fact that --</p> <p>22 that it's the most recent product and it's -- it's a</p> <p>23 12-centimeter sling instead of a longer sling.</p> <p>24 Q. (By Mr. De La Cerda) What's the</p>

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<p>1 significance of it being a shorter sling as opposed</p> <p>2 to a longer sling?</p> <p>3 A. It's -- I decided that if I can do it with</p> <p>4 12 centimeters, I'm not going to use 19 centimeters</p> <p>5 when the evidence is good in my practice.</p> <p>6 Q. Is -- you agree with the general theory that</p> <p>7 less foreign body is better when it comes to these</p> <p>8 types of procedures?</p> <p>9 MR. SNELL: Form.</p> <p>10 A. No, I think that there are physicians that</p> <p>11 have a level of comfort with TVT-O or, for that sake,</p> <p>12 with TVT Retropubic, and that being with a</p> <p>13 5-millimeter needle, a 3-millimeter needle.</p> <p>14 Each physician has his own level of comfort</p> <p>15 and they're going to use what works well for them. I</p> <p>16 have not found any scientific evidence that points out</p> <p>17 to one being better than the other based on that.</p> <p>18 Q. (By Mr. De La Cerda) What about the</p> <p>19 general -- do you agree with the general</p> <p>20 proposition, though, that more foreign body will</p> <p>21 cause more foreign body reaction within the human</p> <p>22 body?</p> <p>23 MR. SNELL: Objection, asked and answered.</p> <p>24 A. It assumes -- it assumes that there's -- the</p>	<p>1 Q. Is the Burch procedure within the standard</p> <p>2 of care?</p> <p>3 A. I think that for a physician that wants to</p> <p>4 do Burch procedures, that may apply.</p> <p>5 Q. You wouldn't criticize another doctor for</p> <p>6 doing a Burch procedure over a synthetic midurethral</p> <p>7 sling; right?</p> <p>8 A. I would not be -- be critical. I can share</p> <p>9 it, the evidence, but there's -- there's no reason for</p> <p>10 being critical over the Burch procedure.</p> <p>11 Q. Are pubovaginal slings using native tissue</p> <p>12 still taught in medical school, to your knowledge?</p> <p>13 A. No, I don't think they are taught -- I</p> <p>14 probably don't know, but I don't think they are.</p> <p>15 Q. And if a physician performed a pubovaginal</p> <p>16 sling using native tissue, would you criticize him or</p> <p>17 her for doing that?</p> <p>18 A. That's -- I have to say that's an excellent</p> <p>19 question because it's -- it probably is the procedure</p> <p>20 that would prompt me to say, "Listen, you need to</p> <p>21 reevaluate on how you're taking care of these</p> <p>22 patients," because that can be a morbid procedure.</p> <p>23 Q. So that one is a little more borderline for</p> <p>24 you?</p>
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<p>1 term "foreign body" probably is the same -- in the</p> <p>2 same area as "gold standard." They're -- they're very</p> <p>3 wide, very unscientific. They -- in terms of the</p> <p>4 material that you leave in the area, if a physician</p> <p>5 would come and ask me, "Do you think I should do this</p> <p>6 because it leaves less material," I could not tell him</p> <p>7 with certainty, "Yes, you definitely need to move from</p> <p>8 one to the other." I have no evidence to support</p> <p>9 that.</p> <p>10 Q. (By Mr. De La Cerda) And so, ultimately,</p> <p>11 you switched to the TVT-ABBREVO just because of your</p> <p>12 personal experience with it?</p> <p>13 A. It's easier -- easier to keep on the shelf,</p> <p>14 the TVT-ABBREVO. If -- I guess, right now, if there</p> <p>15 would be -- there would be only TVT-O, I would be</p> <p>16 perfectly comfortable with it.</p> <p>17 Q. Okay. Do you know whether TVT-ABBREVO comes</p> <p>18 in laser cut or mechanically cut?</p> <p>19 A. Laser -- it comes in laser cut.</p> <p>20 Q. TVT-ABBREVO is only laser cut; right?</p> <p>21 A. Right.</p> <p>22 Q. Do you know whether the Burch procedure is</p> <p>23 still taught in medical school?</p> <p>24 A. I don't know.</p>	<p>1 A. Yes.</p> <p>2 Q. Yeah.</p> <p>3 A. And I can -- I can do that well -- I want to</p> <p>4 think that I can do it well because I did it well at</p> <p>5 one time, it's just that it's -- in terms of morbidity</p> <p>6 and seroma and wound complications and obstruction,</p> <p>7 it's -- it's a different -- different surgery.</p> <p>8 Q. Would you consider it to be within the</p> <p>9 standard of care or no?</p> <p>10 A. I -- I think that in certain areas, probably</p> <p>11 if that's -- we go to areas where they don't have what</p> <p>12 we have, that could be considered standard of care.</p> <p>13 Q. You've never done a study to determine what</p> <p>14 percentage of medical schools are teaching Burch or</p> <p>15 pubovaginal slings using native tissue; right?</p> <p>16 A. No, I don't know that.</p> <p>17 Q. In your career, how many revision or</p> <p>18 excision surgeries involving synthetic midurethral</p> <p>19 slings have you performed?</p> <p>20 A. I -- I think I have done three. I may have</p> <p>21 done more than that. Just in my mind it's -- it's</p> <p>22 infrequent enough that I actually -- one of the</p> <p>23 presentations on the thumb drive is me excising a</p> <p>24 sling, the pictures. That's how infrequent it is.</p>

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<p style="text-align: right;">Page 82</p> <p>1 Q. So to -- I'm sorry, I didn't want to cut you 2 off. 3 A. So I actually consent to the patient and I 4 said, "This is unusual." I consent to the patient to 5 have it removed. 6 Q. Okay. So to your recollection, you've done 7 three revision or excision surgeries involving 8 synthetic midurethral slings? 9 A. I don't want to come into a fault -- faulty 10 memory, but I can recall about three. 11 Q. Okay. Of those three, how many were you 12 able to remove the entire sling? 13 MR. SNELL: Form. 14 A. On the -- it's probably two of them, the 15 entire -- the entire sling being up -- up to the 16 descending pubic ramus in that area. I remove the 17 entirety of it. 18 Q. (By Mr. De La Cerda) And so that was -- 19 that's the portion that is actually under the 20 urethra but not the portion that goes into the pubic 21 ramus; is that right? 22 A. The portion that gets about -- to about 23 1 centimeter from the obturator internus muscle. 24 Q. Okay.</p>	<p style="text-align: right;">Page 84</p> <p>1 internus muscle. 2 Q. And of these three revisionary excisions -- 3 let me first clarify. 4 Are the three revision or excision 5 surgeries, are they all three excision surgeries or 6 revision or both? How would you characterize them? 7 A. They are excisions. I was speaking about 8 removing the whole thing. 9 Q. So those three were excision surgeries. 10 Were those three patients, patients you had 11 implanted the sling or someone else? 12 A. I had one that I implanted the sling and two 13 that came from -- came referred to me. 14 Q. Okay. So to your recollection, and you've 15 implanted 300 synthetic midurethral slings for the 16 last -- per year for approximately the last ten years; 17 right? 18 A. Lately, they're -- the number of slings is 19 less. 20 Q. Okay. So would a fair estimation be that 21 somewhere between 2- and 3,000 synthetic midurethral 22 slings is what you've implanted? 23 A. Yes. 24 Q. Okay. In the last ten years; right?</p>
<p style="text-align: right;">Page 83</p> <p>1 A. So anything that is beyond the obturator 2 internus muscle, I -- I stay away from that. 3 Q. Is that because the risk outweighs the 4 benefit of removing that mesh that's beyond the 5 obturator internus muscle? 6 A. It's -- there are three factors to it. 7 Q. Okay. 8 A. The first one is that the orientation of the 9 tape is very misleading to the surgeon. It comes 10 forward to you and many surgeons, if they're 11 inexperienced, they'll keep digging into the area and 12 cause harm to the lateral side. That's one -- one of 13 the other reasons. 14 The second reason is that I haven't found 15 any -- anything convincing, and I keep looking for 16 anything that has been written about excising that -- 17 that portion of the -- of the tape. 18 And number three is that most of the time, 19 2, 3 percent of the time that we're going to revise a 20 sling for avoiding this function, it makes no -- no -- 21 there's no justification, I should say, there's no 22 justification to go beyond that area. 23 Q. Okay. 24 A. Beyond the area within the obturator</p>	<p style="text-align: right;">Page 85</p> <p>1 A. Yeah, over the last ten years, yeah, that 2 would be accurate. 3 Q. And of those 2- to 3,000 synthetic 4 midurethral slings, your testimony is that you've only 5 excised one of -- you've only, personally, excised one 6 of the slings that you've put in; is that right? 7 A. Yes. That I remember, one. I may -- may 8 have taken a segment or a fiber from another sling 9 that I might have placed. I haven't kept track of it 10 because the reality is that it's extremely rare. I'm 11 going to tell you, what happens most of the time is 12 you put the sling, the patient comes in, she's dry, 13 she's happy, she moves on. 14 Q. What were the reasons why you performed the 15 three excision surgeries that you can recall? 16 A. One of them was -- was just a tight sling on 17 the patient. A young patient with a tight sling and 18 she was having difficulty urinating. 19 I recall one -- another one was someone with 20 a sling that was not a mid-urethra, it was higher. 21 The sling was placed higher than the urethra and it 22 wasn't working and I took that one and put one in the 23 urethra. 24 Q. Any other reason that you can recall?</p>

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<p>1 A. No. I had -- I had one that came in because</p> <p>2 she had -- she had pain on the area of the insertion</p> <p>3 of the sling.</p> <p>4 Q. Okay. So you had one with pain -- have you</p> <p>5 ever removed a synthetic midurethral sling because of</p> <p>6 an erosion?</p> <p>7 A. Yes, I have. I have removed that erosion</p> <p>8 and I actually had one that I didn't put in -- put in</p> <p>9 those three. Now I recall one that she broke the</p> <p>10 incision and when I saw the patient coming on the</p> <p>11 third week, on the third week, I asked her, "How is it</p> <p>12 working?" She said, "Well, it's working."</p> <p>13 And I examine her and she -- she had an</p> <p>14 exposure on the -- on the sling. She was honest --</p> <p>15 honest enough to tell me, "Doctor, I was at home</p> <p>16 eating, I was choking on food and I threw myself over</p> <p>17 a chair and I felt -- I felt something." So she broke</p> <p>18 the incision line, and I saw it and I said, "Okay,</p> <p>19 well, I'll -- I recommend that you have this removed."</p> <p>20 Q. So is that the -- is your testimony that's</p> <p>21 the only exposure -- or that circumstance you just</p> <p>22 mentioned, is that the only exposure where erosion of</p> <p>23 a synthetic midurethral slings that you had to treat?</p> <p>24 A. No, I had a couple of exposures in the -- in</p>	<p>1 Q. Have you ever performed an excision surgery</p> <p>2 or revision surgery because the patient was suffering</p> <p>3 from dyspareunia?</p> <p>4 MR. SNELL: Form.</p> <p>5 A. I -- I did one, same one that was having --</p> <p>6 Q. (By Mr. De La Cerda) Pain?</p> <p>7 A. -- the pain, yeah.</p> <p>8 Q. Got it. Okay.</p> <p>9 All right. The TVTs and the TVT-Os that</p> <p>10 you've placed, those have involved -- or have been</p> <p>11 mesh that is mechanically cut mesh and mesh that is</p> <p>12 laser cut mesh; right?</p> <p>13 A. Both.</p> <p>14 Q. Did that have anything to do with the time</p> <p>15 period in which you were implanting it or do you</p> <p>16 just -- did you stock both or what did that have to</p> <p>17 do -- any factors that that had to do with?</p> <p>18 A. No, I did not have any specific reason to</p> <p>19 choose one over the other.</p> <p>20 Q. Okay. Over the last ten years you performed</p> <p>21 surgeries to correct pelvic organ prolapse; right?</p> <p>22 A. Yes.</p> <p>23 Q. What types of surgeries have you performed?</p> <p>24 A. I have performed anterior repairs, posterior</p>
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<p>1 the past, but it's something that either you give</p> <p>2 estrogen or you just take the fibers with a tenotomy</p> <p>3 scissors, which are using in reconstructive surgery,</p> <p>4 actually they're used in the eye and they have --</p> <p>5 they're just perfect for this.</p> <p>6 Q. I guess my crude understanding of that is</p> <p>7 it's like an in-office trimming of the exposed mesh;</p> <p>8 is that right?</p> <p>9 A. It's -- you may have a few segments. In</p> <p>10 other words, you have not seen the whole incision open</p> <p>11 up.</p> <p>12 Q. Okay.</p> <p>13 A. And I -- I do remember a long time ago I saw</p> <p>14 a patient with a segment on one side. That's the only</p> <p>15 one I remember that the exposure was not in the</p> <p>16 midline on the incision. And that patient, I tried to</p> <p>17 convince her to let me take it and she said, "No,</p> <p>18 you're not going to take anything because it's not</p> <p>19 bothering me."</p> <p>20 Q. So these are -- these are done -- this</p> <p>21 procedure you just mentioned, this trimming of the</p> <p>22 sling is done in-office, not under general anesthesia</p> <p>23 in surgery; right?</p> <p>24 A. Right.</p>	<p>1 repairs, enterocele repairs, iliococcygeal suspension,</p> <p>2 sacral spinous ligamentous suspension, abdominal</p> <p>3 sacrocolpopexies, robotic sacrocolpopexies, Prolift,</p> <p>4 graft reinforced repair with biologicals, augmented</p> <p>5 repairs with Gynemesh, perineoplasty.</p> <p>6 I think I have mentioned probably all of</p> <p>7 them.</p> <p>8 Q. The anterior and posterior repairs, did</p> <p>9 those include colporrhaphies?</p> <p>10 A. Yes.</p> <p>11 Q. Are those synonymous or --</p> <p>12 A. Pretty much, yes.</p> <p>13 Q. Okay. Now, all the repairs that you just</p> <p>14 mentioned, those are all within the standard of care;</p> <p>15 right?</p> <p>16 A. Yes.</p> <p>17 Q. Is implanting transvaginal mesh -- strike</p> <p>18 that.</p> <p>19 Is implanting synthetic polypropylene mesh</p> <p>20 transvaginally still within the standard of care?</p> <p>21 MR. SNELL: Form.</p> <p>22 A. It's still within the standard of care if it</p> <p>23 will have the product available.</p> <p>24 Q. (By Mr. De La Cerda) As of now, from the</p>

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<p>1 Ethicon products, Gynemesh is still available; 2 right? 3 A. Gynemesh is still available. 4 Q. And do you -- is it your opinion that it's 5 still within the standard of care to implant Gynemesh 6 transvaginally for the treatment of pelvic organ 7 prolapse? 8 A. I believe it changed, the actual indication 9 or clearance. I may have read that. 10 Q. So the indication now is to use it for 11 abdominal sacrocolpopexies; right? 12 A. Yes. 13 Q. So is it within the standard of care, 14 though, to implant Gynemesh -- I'm talking about 15 today -- so is it as of today within the standard of 16 care to implant Gynemesh transvaginally for the 17 treatment of pelvic organ prolapse? 18 A. Not -- not today. 19 Q. Okay. 20 A. Based on what I just stated. 21 Q. Okay. What was -- what was for you an 22 indication in the past to implant synthetic mesh 23 transvaginally for the treatment of pelvic organ 24 prolapse as opposed to doing one of the other non-mesh</p>	<p>1 transvaginal mesh for pelvic organ prolapse? 2 A. Yes, I have. 3 Q. And how many have you done of that? 4 A. I look at those and they may be in the -- in 5 the 10, 20, may be right -- right there based on what 6 I saw the last time. 7 Q. So approximately 10 to 20 in your career 8 revision or excision surgeries involving synthetic 9 polypropylene transvaginal mesh? 10 A. That's -- that's a ballpark figure, yes. 11 That's a very general figure. 12 Q. And of those 10 to 20, how many were you 13 able to remove the entire mesh device? 14 MR. SNELL: Form, foundation. 15 A. In most of them -- most of them you can 16 dissect the space -- the same space where you place it 17 and you can -- you can remove it. It's -- if you have 18 it in the muscle, obviously that's -- I already stated 19 that there is no benefit of doing that. But if you 20 dissect that area, you bring it up and you 21 hydrodissect your segments, you're -- you can remove 22 most of it. 23 Q. (By Mr. De La Cerda) Have you ever 24 performed a revision or excision surgery because the</p>
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<p>1 procedures that you've mentioned? 2 A. I -- I came to the clinical appreciation 3 that patients that have had a hysterectomy, patients 4 that have had recurrent prolapse, patients that had a 5 high degree of exertion, and patients that have a 6 recurrent compartment or a contralateral compartment 7 defect, those patients benefit from it. 8 I -- that's the general. I knew that I had 9 patients that have -- I had one shot to take to the 10 operating room and I -- for whatever reason, and those 11 are the most difficult ones because they were more 12 complicated, but on the other side, you wanted to give 13 her the durability of the repair. 14 That's -- that's in general what I -- what I 15 use when I counsel someone on the -- on the use of 16 this synthetic graft. We started -- we started 17 reading then, around the time that we had Gynemesh, 18 more and more about durability and the repairs, 19 specifically for those apical -- apical defects, so it 20 became very attractive to treat patients on the 21 apical, with apical defects, and when we didn't have 22 to do an incision. 23 Q. Have you ever performed revision or excision 24 surgeries involving synthetic polypropylene</p>	<p>1 patient was reporting pain and this is, again, I'm 2 talking about patients with transvaginal mesh for 3 pelvic organ prolapse? 4 A. You know, pain -- pain is rare after this 5 kind of repair. What most frequently happen is that 6 you would get in to have -- to remove an exposure, and 7 then you end up -- you ended up removing more than 8 what you thought you were going to remove because you 9 had the plane and you were just dissecting the area 10 and remove it. Then you ended up reinforcing the area 11 with sutures. 12 There are times in which I -- I -- I say I 13 have to do something to support it and it becomes such 14 a subjective thing that I wish I could have explained 15 this not now, but even when doctors would ask me the 16 same questions and -- and be accurate and precise 17 about it, but no, it's a general -- it's a general 18 idea. What I'm explaining now is a general idea of 19 what happens in the operating room when you're going 20 to remove it. So you start small, but you start 21 extending yourself on the dissection. 22 Q. So of the 10 to 20, though, how many of 23 those did you remove for the reason of that they 24 had -- they were experiencing pain?</p>

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<p>1 A. It's -- I think it's rare. I can't give you</p> <p>2 a specific number without -- okay, I want to be</p> <p>3 accurate and precise, but it was rare. The most</p> <p>4 recurring reason was an exposure.</p> <p>5 Q. Okay. And did they report exposure with</p> <p>6 pain or no?</p> <p>7 A. No. No. They -- most frequent complaint</p> <p>8 with the exposure was vaginal discharge.</p> <p>9 Q. So were the 10 to 20 excision surgeries,</p> <p>10 were those primarily because of exposures?</p> <p>11 A. It's -- it's -- mostly exposure and</p> <p>12 symptomatic exposures, exposures in which you saw</p> <p>13 granulation tissue.</p> <p>14 Q. Of granulation tissue, okay.</p> <p>15 Were any of the excision procedures</p> <p>16 performed specifically because of dyspareunia?</p> <p>17 A. No, I don't remember anyone specific on</p> <p>18 dyspareunia. I remember taking one Prolift that was</p> <p>19 dyspareunia and pain.</p> <p>20 Q. Have you ever -- have you ever had a patient</p> <p>21 come to you reporting dyspareunia or pain after having</p> <p>22 had a transvaginal mesh or pelvic organ prolapse where</p> <p>23 you believed it was the transvaginal mesh causing the</p> <p>24 pain or dyspareunia?</p>	<p>1 your career?</p> <p>2 A. Definitely more than 100.</p> <p>3 Q. Between 100 and 200?</p> <p>4 A. Easily.</p> <p>5 Q. How many Prosimas have you implanted in your</p> <p>6 career?</p> <p>7 A. I did about 50.</p> <p>8 Q. Okay. Turning -- we've now been going</p> <p>9 another hour. Would you like to take a break?</p> <p>10 A. Yes, just quick as before.</p> <p>11 (Thereupon, a recess was taken from</p> <p>12 10:21 a.m. until 10:29 a.m., after which the</p> <p>13 following proceedings were held:)</p> <p>14 Q. (By Mr. De La Cerda) Okay. We are back</p> <p>15 on the record.</p> <p>16 Doctor, I wanted to direct your attention</p> <p>17 back to your CV, please, which is Exhibit 13. Just a</p> <p>18 couple quick things. If you'll turn to the fourth</p> <p>19 page, the section which is "Courses Presented."</p> <p>20 A. Yes.</p> <p>21 Q. The entities that I've seen -- well, the</p> <p>22 entities that are mentioned within this section where</p> <p>23 you've presented a course, the only entities I've seen</p> <p>24 mentioned are Johnson & Johnson, Ethicon Endo and</p>
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<p>1 A. No. Most of the patients that we see with</p> <p>2 dyspareunia, in a busy vaginal surgery practice, is</p> <p>3 without mesh.</p> <p>4 Q. So you've never had that happen where you</p> <p>5 believed the dyspareunia was being caused by the</p> <p>6 transvaginal mesh; right?</p> <p>7 A. By -- specifically by transvaginal mesh, no.</p> <p>8 Q. Same question for the -- I don't know if I</p> <p>9 asked you for the slings, but have you ever had a</p> <p>10 patient come to you reporting pelvic pain or</p> <p>11 dyspareunia after having had a synthetic midurethral</p> <p>12 sling where you believed that it was the sling causing</p> <p>13 that pain or dyspareunia?</p> <p>14 A. No, I -- I saw one sling that was low enough</p> <p>15 that I -- it could -- that could have been the source</p> <p>16 of dyspareunia.</p> <p>17 Q. Okay. And I guess really you're thinking</p> <p>18 it's more the positioning of the sling as opposed to</p> <p>19 the actual sling; right?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. How many Gynemesh PS's have you</p> <p>22 implanted in your practice, in your career?</p> <p>23 A. Over a hundred.</p> <p>24 Q. And how many Prolifts have you implanted in</p>	<p>1 Ethicon.</p> <p>2 Are there any other entities mentioned here</p> <p>3 or no?</p> <p>4 A. No, I never worked outside of Ethicon for</p> <p>5 any another company.</p> <p>6 Q. Then under "Research Experience," which is,</p> <p>7 I guess, a couple pages later, is there -- do you have</p> <p>8 listed here any research on transvaginal polypropylene</p> <p>9 midurethral slings or transvaginal polypropylene</p> <p>10 pelvic organ prolapse mesh?</p> <p>11 A. No, I did not do research on transvaginal</p> <p>12 sling. I rely on the randomized control trials.</p> <p>13 Q. And then under "Presentations and</p> <p>14 Publications as Author or Coauthor," I didn't see any</p> <p>15 presentations or publications that involve</p> <p>16 transvaginal polypropylene midurethral slings or</p> <p>17 transvaginal polypropylene mesh for pelvic organ</p> <p>18 prolapse; is that right?</p> <p>19 A. Yes, I did not -- I did not publish on</p> <p>20 transvaginal slings.</p> <p>21 Q. We can set that aside for a second.</p> <p>22 Okay. You're not a biomedical engineer;</p> <p>23 correct?</p> <p>24 A. I -- I have a very good understanding of</p>

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<p style="text-align: right;">Page 98</p> <p>1 biomedical engineering.</p> <p>2 Q. Okay. Would you consider yourself a</p> <p>3 biomedical engineer?</p> <p>4 A. I do not get compensated for doing</p> <p>5 biomedical engineering.</p> <p>6 Q. Okay.</p> <p>7 A. And I did not graduate from -- with a degree</p> <p>8 of biomedical engineering. I do -- I do understand</p> <p>9 biomedical engineering well.</p> <p>10 Q. I saw that you brought some books here that</p> <p>11 would relate to that, I believe. What is it that</p> <p>12 would provide the basis for your belief that you have</p> <p>13 expertise in biomedical engineering?</p> <p>14 A. I have devoted years to understand it, to</p> <p>15 read about it beyond what any other physician that I</p> <p>16 ever met have done.</p> <p>17 Q. Anything else?</p> <p>18 A. I have studied, I have spoken to biomedical</p> <p>19 engineers, but specifically it's a passion and a</p> <p>20 dedication that I have had to understand it.</p> <p>21 Q. Would you consider yourself an expert on the</p> <p>22 design of medical devices?</p> <p>23 A. It goes right along with the biomedical</p> <p>24 engineering, with the surgical expertise that allows</p>	<p style="text-align: right;">Page 100</p> <p>1 Q. Were you ever designed -- were you ever</p> <p>2 involved in the design of any transvaginal mesh</p> <p>3 devices?</p> <p>4 A. Not in the devices of the ones that I use.</p> <p>5 Q. Do you have any patents on medical devices?</p> <p>6 A. No.</p> <p>7 Q. Do you know what the standard is for a --</p> <p>8 that a manufacturer must follow in designing mesh</p> <p>9 products?</p> <p>10 A. I'm -- I became very familiarized with --</p> <p>11 when I was with Ethicon by my own inquiries.</p> <p>12 Q. What standards did Ethicon employ in the</p> <p>13 design of its mesh products?</p> <p>14 A. It's -- it was from the initiation, from</p> <p>15 what they had an idea of what the device was, what the</p> <p>16 need was, and then there were -- I know there was a</p> <p>17 structure for research and development with the</p> <p>18 running of different -- different trials at different</p> <p>19 levels. And I get that information and submit it,</p> <p>20 along with other information that I was -- in which --</p> <p>21 that had nothing to do with surgery, but cytotoxicity,</p> <p>22 paragenicity assays, cell cultures assays, and all</p> <p>23 this information submitted to the FDA, who would then</p> <p>24 review it and -- and within its own division for the</p>
<p style="text-align: right;">Page 99</p> <p>1 me to see what -- what can save in terms of efficiency</p> <p>2 in the operating room, what can I do better for my</p> <p>3 patients. That's what I use this for. This allows me</p> <p>4 to understand the design better.</p> <p>5 Q. Have you ever, personally, designed a</p> <p>6 medical device?</p> <p>7 A. I -- not -- not a medical device, but I have</p> <p>8 my own set of needles that I actually had made.</p> <p>9 Q. What were those needles for?</p> <p>10 A. For -- to approach the deep space in the</p> <p>11 pelvis.</p> <p>12 Q. Were those used in connection with</p> <p>13 implanting mesh at all?</p> <p>14 A. No, I use them for sutures.</p> <p>15 Q. Okay. Have you ever been involved in the</p> <p>16 design of a medical device?</p> <p>17 A. I -- I did give input to the design. It was</p> <p>18 not -- it was not my own patent.</p> <p>19 Q. And what device was that?</p> <p>20 A. Staplers for -- for -- staplers, a</p> <p>21 retractor, again, a circumferential needle.</p> <p>22 Q. And these are all devices that are used in</p> <p>23 connection with surgery?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 101</p> <p>1 device and then get back to them.</p> <p>2 Q. Do you know what a manufacturer researches</p> <p>3 before a product is designed or released?</p> <p>4 MR. SNELL: Form, overbroad.</p> <p>5 A. The --</p> <p>6 Q. (By Mr. De La Cerda) Let's take it a</p> <p>7 little more specific to the mesh products.</p> <p>8 What did -- what, to your knowledge, did</p> <p>9 Ethicon research in regard to its mesh products before</p> <p>10 they were released?</p> <p>11 A. I know that they -- they went through their</p> <p>12 suture -- suture research and -- and I know that they</p> <p>13 did experiments short term and long term with sutures.</p> <p>14 I know that there was an opinion acquired</p> <p>15 from the field on the use of different sutures. Then</p> <p>16 there was a -- there was a use on the type of mesh</p> <p>17 that was used for prolapse on the different types of</p> <p>18 meshes. That wasn't done in the United States, that</p> <p>19 was done in France.</p> <p>20 And there was also -- the materials were</p> <p>21 even evaluated in the same -- in the same way that</p> <p>22 sutures are evaluated, but also in the operating room.</p> <p>23 I'm aware of that one, too.</p> <p>24 I'm aware that the needles and the approach</p>

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<p>1 that was used was evaluated by them before it was even 2 used in the United States. And I know the packaging, 3 the packaging was evaluated. I was able to see how 4 they design the package for the operating room. 5 So all those lines never got to the place 6 where they actually do the knitting of the material, 7 never -- never got to see that, but I know there was a 8 facility for that. 9 So there was a step of -- actually quite an 10 elaborate chain that ended up giving the product. 11 Q. Do you know what types of experts were 12 involved in the design of Ethicon's mesh products? 13 A. I spoke to materials engineers. I actually 14 enjoy very much when I interacted with one of the 15 biomechanical engineers over there that had a doctor's 16 degree on biomaterials and I actually -- and I enjoyed 17 that. I look at different -- they asked me for 18 different types of materials. We look at -- they got 19 my input on fibers. 20 I know that there was another group in 21 France that was using those materials. One thing that 22 I observed is that it would not just go with just one 23 opinion, it was a consensus of different surgeons and 24 different -- different settings.</p>	<p>1 devices. I had an idea of the classification of the 2 devices and I had an idea, because I use other types 3 of -- of devices that have nothing to do with mesh. 4 Q. What's your understanding of the 5 classifications of devices? 6 A. I knew that heart -- heart monitors and 7 nerve stimulators and intermittent nerve stimulator 8 had a different classification than our meshes had and 9 that surgical instruments would have and that sutures 10 would have. You can -- you can just open -- you go to 11 the operating room and get into one of the boxes of 12 the sutures and you can pull that paper that gives all 13 these different things about the sutures. So it's -- 14 I knew I had -- I had an idea of the different -- at 15 least three classifications that were used. 16 Q. Some requiring testing before they go out on 17 the market, some perhaps not; right? 18 MR. SNELL: Form. 19 A. Some methods -- some methods did require 20 different type -- different types of testing, 21 different -- each one had different requirements. 22 Q. (By Mr. De La Cerda) Do you know how 23 pelvic organ prolapse, transvaginal synthetic 24 polypropylene mesh is currently classified?</p>
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<p>1 Q. Do you remember the names of any of the 2 folks that you interacted with on those issues? 3 A. I can't -- I can't remember because it's 4 over -- over five years and, you know, it's -- it 5 wasn't a friendship that would continue beyond that. 6 It was a work relationship. 7 Q. Do you know what a "design history file" is? 8 A. No. 9 Q. Are you familiar with industry standards 10 that govern medical device design? 11 A. I read at one time, I read that. I read 12 about ISO testing. I read about ISO testing. I read 13 about the different toxicity assays and, actually, at 14 one time I even may have read about the testing that 15 was done for -- for meshes that was using sutures, 16 i.e., I actually research it and read about it. 17 Q. Anything else that you can recall? 18 A. No. 19 Q. I'm sorry, is that -- 20 A. I'm sorry. Not at this moment. 21 Q. Are you familiar with regulatory standards 22 that govern medical devices? 23 A. I became -- I became aware of the regulatory 24 standards. I knew about the classifications of</p>	<p>1 A. It's -- I read, recently, the classification 2 for prolapse meshes and for -- they went up to 3 Class 3. 4 Q. And what does that mean to your 5 understanding? 6 A. They are classified as high-risk devices. 7 Q. Do you agree with that? 8 A. I -- I'll -- I agree with the approval that 9 the FDA has and I'm not going to challenge the FDA or 10 their panel on that one. 11 Q. Fair enough. Would you -- are you an expert 12 in polymer chemistry? 13 A. I -- I don't design polymer chemicals. I do 14 understand certain -- the polymers that are used in my 15 specialty. 16 Q. And what polymers would those be? 17 A. When it comes down to polymers used in my 18 specialty, it's polypropylene. 19 Q. Are you an expert in surgical pathology? 20 A. That -- that's an average over the last 25 21 years, I do look at slides. 22 Q. And that would -- that would be the basis 23 for you stating that you had expertise in surgical 24 pathology; is that right?</p>

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<p>1 A. I think that everyone that is a surgeon 2 needs to have an expertise in surgical pathology. 3 Q. Okay. So that would be your basis for 4 saying that; right? 5 A. That's correct. 6 Q. I didn't ask you this. What would be your 7 basis for saying you have expertise in polymer 8 chemistry, is it your experience? 9 A. My experience and what I read, the time that 10 I devote, the time that I have devoted over the years 11 to look at sutures and specifically polypropylene. 12 Q. Have you ever personally done chemical tests 13 to determine if polypropylene mesh degrades? 14 A. I have not personally done -- done that 15 testing. I did -- I did -- I have -- I read about it 16 and have considered that hypothesis. 17 Q. Have you ever done a microscopic analysis of 18 explanted polypropylene mesh to determine if the mesh 19 degraded personally? 20 A. Not -- not with the purpose of degradation 21 because I still -- I still looking for what -- what 22 does degradation really mean in the pathology 23 specimen. 24 Q. Okay. I'm going to shift gears a little</p>	<p>1 essentially what -- what could happen that is within 2 my control that is -- and what's not in my control and 3 patients appreciate that we do that. 4 Q. (By Mr. De La Cerda) A physician should 5 warn his patient -- his or her patient of 6 characteristics of the transvaginal mesh or sling 7 product that can significantly increase their risk 8 of severe complications; correct? 9 MR. SNELL: Form, foundation. 10 A. On that counseling, the counseling should 11 involve what has been tested. In other words, the 12 last thing that you want as a patient is to be 13 overwhelmed by just a wealth of data that is not 14 clinically relevant, and we -- we have studies that 15 actually address that. 16 Q. (By Mr. De La Cerda) So I think we might 17 be getting to something there. If -- if a 18 characteristic of a transvaginal mesh or sling 19 product is clinically relevant, should that be 20 disclosed to a patient during the informed consent 21 process? 22 MR. SNELL: Same objection, foundation. 23 A. The informed consent addresses that. 24 Q. (By Mr. De La Cerda) So is that a "yes"?</p>
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<p>1 bit. 2 Would it be fair to say that before a 3 physician decides to utilize a transvaginal 4 polypropylene mesh or sling to treat a patient, that 5 it's necessary for the physician to warn the patient 6 of all known side effects of the product, including 7 severe ones? 8 MR. SNELL: Objection, form, speculation. 9 A. I think that before any -- any surgery, 10 there has to be -- there has to be a full 11 understanding of the -- as part of the informed 12 consent. And when -- when that's happening, there -- 13 there are factors that are going to play into it. 14 Yes, ideally, we should be able to clear our 15 patients and get -- get a full understanding of it. 16 There are times in which the patient cannot understand 17 it and we have to find, as physicians and surgeons, a 18 way to get them through the most relevance. But that 19 including -- includes surgery with or without mesh. 20 Q. (By Mr. De La Cerda) Okay. So do you 21 think that all the known side effects, including 22 severe ones, should be disclosed to patients? 23 MR. SNELL: Same objection, form. 24 A. It's all known -- not only side effects, but</p>	<p>1 A. That would be in general a yes within -- 2 within the parameters of that conversation between the 3 physician and the -- and the patient. So it would be 4 a yes with a condition that with knowing that that's 5 very unique. That's a very unique interaction. 6 Q. Okay. Do you agree that a physician has a 7 duty to inform his or her patients of the material 8 risks associated with a transvaginal mesh or sling 9 product before it's implanted in the patient? 10 MR. SNELL: Form, foundation, overbroad. 11 A. I -- I -- my opinion is that the patient 12 should be informed not only of -- of the mesh, but 13 if -- if surgery is being done with sutures, the 14 patient should know that, too. 15 Q. (By Mr. De La Cerda) I mean, what I'm 16 trying to do is use different terms for the risks or 17 complications and in this one I'm using material 18 risks associated with transvaginal mesh or sling 19 product. Do you think that material risks should be 20 disclosed to the patient? 21 MR. SNELL: Same objection, vague, 22 immaterial. 23 A. Just to clarify, are you talking about the 24 material or the material risk?</p>

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<p>1 Q. (By Mr. De La Cerda) That's a good</p> <p>2 question.</p> <p>3 Material, that term I'm using -- because</p> <p>4 there's different ways that we've seen risks and</p> <p>5 complications associated with mesh products described</p> <p>6 by physicians. Sometimes they describe those risks as</p> <p>7 material risks, not as the material polypropylene, but</p> <p>8 as being relevant risks.</p> <p>9 A. Oh.</p> <p>10 Q. They're using that word.</p> <p>11 A. I understand.</p> <p>12 Q. That's a good question. Some doctors have</p> <p>13 used the term "material risk," "Yeah, I disclose it if</p> <p>14 it was a material risk."</p> <p>15 Now with that explanation, do you believe</p> <p>16 that material risks associated with these products</p> <p>17 should be disclosed during the informed consent</p> <p>18 process?</p> <p>19 MR. SNELL: Same objection.</p> <p>20 A. The material risk associated with the whole</p> <p>21 extent of the procedure should be -- should be</p> <p>22 disclosed.</p> <p>23 Q. (By Mr. De La Cerda) Okay. You mentioned</p> <p>24 the term "clinically relevant." Is that the same</p>	<p>1 patient to make a determination of whether she wants</p> <p>2 to undergo the surgery; right?</p> <p>3 A. It's -- patients are going -- are going to</p> <p>4 eventually follow your -- the -- the doctor, the</p> <p>5 doctor's advice. But the reason why you do the</p> <p>6 informed consent is, more than the patient deciding,</p> <p>7 which many times they -- they cannot decide, it's to</p> <p>8 empower that patient with the information of this is</p> <p>9 what I use for my decision, the decision that I</p> <p>10 recommended to you.</p> <p>11 Q. Okay. Ultimately, though, it is -- the</p> <p>12 patient has the right to decide one way or another</p> <p>13 what they want to do; right?</p> <p>14 MR. SNELL: Form, overbroad.</p> <p>15 A. Patient -- patients may -- may ask more</p> <p>16 questions or may -- say "I will have a preference,"</p> <p>17 but in 25 years seeing patients, patients will tell --</p> <p>18 will ask you, "Doctor, tell me what you -- you think</p> <p>19 is the best way of doing it and tell me why and how</p> <p>20 you come to that decision."</p> <p>21 Q. (By Mr. De La Cerda) Okay. So have you</p> <p>22 ever had a patient say, after being consented or</p> <p>23 receiving informed consent, saying, "No, I don't</p> <p>24 want to have that procedure," as to mesh?</p>
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<p>1 thing as clinically significant?</p> <p>2 A. Um, clinically relevant is statistically</p> <p>3 significant.</p> <p>4 Q. Could you explain what that means, what your</p> <p>5 understanding is of that?</p> <p>6 A. It's -- with the best level of evidence that</p> <p>7 we have for what we're doing, explain to the patient</p> <p>8 this is -- we're going to translate it from the</p> <p>9 statistically significant to what's common and what's</p> <p>10 relevant in the surgery.</p> <p>11 Q. Okay. I'm going to try and ask this</p> <p>12 properly.</p> <p>13 Do you agree that a physician should warn</p> <p>14 his or her patients of risks or complications</p> <p>15 associated with the transvaginal mesh or sling</p> <p>16 products that are clinically relevant or statistically</p> <p>17 significant?</p> <p>18 MR. SNELL: Form.</p> <p>19 A. For the whole extent of the procedure.</p> <p>20 Q. (By Mr. De La Cerda) Including the</p> <p>21 products, though; right?</p> <p>22 A. Including the products.</p> <p>23 Q. Okay. Now, the purpose of warning a patient</p> <p>24 during the informed consent process is to allow that</p>	<p>1 A. No, I -- I have not had that experience.</p> <p>2 Q. Do you agree it's important for the</p> <p>3 physician to have as much information about the risks</p> <p>4 associated with transvaginal mesh or sling product so</p> <p>5 that the physician can make an informed decision on</p> <p>6 whether to recommend those products?</p> <p>7 A. I think it's important that the physician</p> <p>8 gets accurate and makes a reasonable effort to get</p> <p>9 better on what they use and what they do every single</p> <p>10 day.</p> <p>11 Q. Including the information that they are</p> <p>12 going to communicate to the patient; right?</p> <p>13 A. It's especially if you're going to</p> <p>14 communicate to the patient and -- especially when it</p> <p>15 has to do with you making a clinical decision.</p> <p>16 Q. Do you agree that physicians rely on a</p> <p>17 transvaginal mesh manufacturer to provide them with</p> <p>18 information about the risks and complications</p> <p>19 associated with their transvaginal mesh products?</p> <p>20 MR. SNELL: Objection, overbroad and</p> <p>21 requires speculation.</p> <p>22 A. I can't -- I cannot think for all the</p> <p>23 physicians, but I -- I can tell you that their</p> <p>24 responsibility is within ourselves before we use any</p>

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<p>1 product.</p> <p>2 Q. (By Mr. De La Cerda) Do you agree the</p> <p>3 transvaginal mesh manufacturers are at least one</p> <p>4 source of information that a physician can rely on</p> <p>5 in obtaining information about their risks and</p> <p>6 complications of transvaginal mesh products?</p> <p>7 MR. SNELL: Objection, speculation.</p> <p>8 A. It might be at the low end of the -- of the</p> <p>9 evidence that we gather.</p> <p>10 Q. (By Mr. De La Cerda) You're not saying</p> <p>11 that a physician shouldn't rely on information from</p> <p>12 a transvaginal mesh manufacturer about the risks and</p> <p>13 complications of those products; right?</p> <p>14 MR. SNELL: Form, overbroad.</p> <p>15 A. I think that a physician needs to rely on</p> <p>16 the best evidence, best clinical evidence, not just in</p> <p>17 any sort of marketing communication or sales</p> <p>18 communication. They need to know that the decision to</p> <p>19 do surgery is a scientific process and they need to</p> <p>20 read that.</p> <p>21 Q. (By Mr. De La Cerda) If -- but certainly</p> <p>22 if a transvaginal mesh manufacturer is providing a</p> <p>23 serious warning about its products, even if that</p> <p>24 warning hasn't played out in the scientific</p>	<p>1 hypothetical.</p> <p>2 Q. (By Mr. De La Cerda) The answer is of</p> <p>3 course; right?</p> <p>4 MR. SNELL: I don't know about that. I</p> <p>5 mean, that's the doctor's answer, but my</p> <p>6 objection is incomplete hypothetical, purely</p> <p>7 speculative.</p> <p>8 Go ahead.</p> <p>9 A. The explosion thing is a little out there.</p> <p>10 It's -- we have not seen any devices that actually</p> <p>11 explode for prolapse or incontinence. I don't know</p> <p>12 for the other ones.</p> <p>13 The point I'm trying to come across is, to</p> <p>14 answer your question, when we look at information, we</p> <p>15 look at randomized control trials. Now, randomized</p> <p>16 control trials in cohort studies, even case control</p> <p>17 studies, you can go down to a list and you're going --</p> <p>18 the methodology is what allows you to give</p> <p>19 recommendations and form your counseling.</p> <p>20 Q. (By Mr. De La Cerda) So even if the</p> <p>21 manufacturer knows of severe life-altering</p> <p>22 complications associated with its products, if that</p> <p>23 severe life-altering complication hasn't played out</p> <p>24 in the randomized control trials, you believe that</p>
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<p>1 literature, I mean, that's still something that</p> <p>2 needs to be considered; right?</p> <p>3 MR. SNELL: Form, overbroad.</p> <p>4 A. There's a degree of information that you</p> <p>5 need to consider. You -- you have -- you're a doctor</p> <p>6 and you have the scientific information because that</p> <p>7 allows you to analyze information better. So in that</p> <p>8 regard, what we're going to see is information that is</p> <p>9 relevant because they're at the highest level of</p> <p>10 evidence, information that is less relevant because</p> <p>11 they are the lowest one, but there's a -- there's a</p> <p>12 hierarchy -- did I say that word okay? -- there is a</p> <p>13 hierarchy of information and we're going to go for the</p> <p>14 highest one.</p> <p>15 Q. (By Mr. De La Cerda) Okay. Let's take a</p> <p>16 silly example for a second. If the manufacturer of</p> <p>17 transvaginal mesh knows that there's a</p> <p>18 one-in-a-million chance that it explodes inside a</p> <p>19 human body, but that is never played out in the</p> <p>20 RCTs, never, ever been seen by anyone other than the</p> <p>21 manufacturer, does that information need to be put</p> <p>22 out to the public and told to physicians?</p> <p>23 MR. SNELL: Objection. I'm going to have to</p> <p>24 object, incomplete, purely speculative,</p>	<p>1 physicians shouldn't place much weight on that?</p> <p>2 A. I think as humans -- as humans, if we see</p> <p>3 that there is any -- any danger for anyone, for any</p> <p>4 other human being, we'll just go and say it,</p> <p>5 regardless of who we work for. And at the end it's</p> <p>6 not a company, it's a group of people working. So the</p> <p>7 human -- the human nature is to -- the human thing is</p> <p>8 to actually do that, and that's our nature. But</p> <p>9 that's different from having -- making a clinical</p> <p>10 decision.</p> <p>11 Q. Okay. So, ultimately, should information</p> <p>12 like that, if it's known to manufacturer, but it</p> <p>13 hasn't played out in the randomized control trials,</p> <p>14 should information like that about severe</p> <p>15 life-altering complications be communicated to a</p> <p>16 patient during the informed consent process?</p> <p>17 MR. SNELL: Form, asked and answered.</p> <p>18 A. What we're going to use to counsel patients</p> <p>19 is randomized control trials. And if -- if the</p> <p>20 question is if the manufacturer should disclose it,</p> <p>21 I -- I -- my opinion is probably most people would go</p> <p>22 ahead and disclose it, but in terms of making a</p> <p>23 clinical decision, we're going to use for the best</p> <p>24 evidence that we have.</p>

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<p>1 Q. (By Mr. De La Cerda) And I understand, I</p> <p>2 definitely understand. I guess what I'm trying to</p> <p>3 get at, though, is: Should that information be</p> <p>4 communicated to the patient during the informed</p> <p>5 consent process or not?</p> <p>6 A. Only the information that is backed by good</p> <p>7 science.</p> <p>8 Q. Okay. So the answer is; no, right?</p> <p>9 MR. SNELL: Objection, asked and answered.</p> <p>10 A. If it's not -- if it's not backed by</p> <p>11 science, it plays no role in the counseling of a</p> <p>12 patient.</p> <p>13 Q. (By Mr. De La Cerda) Including if the</p> <p>14 manufacturer has discovered severe life-altering</p> <p>15 complications that it knows of, even though it</p> <p>16 hasn't been played out in the randomized control</p> <p>17 trials and the medical literature; right?</p> <p>18 A. Our counseling --</p> <p>19 MR. SNELL: Same objection.</p> <p>20 A. Our clinical counseling is evidence-based.</p> <p>21 Q. (By Mr. De La Cerda) Okay. And evidence</p> <p>22 from the manufacturer wouldn't necessarily count --</p> <p>23 well, the finding of a manufacturer as to a severe</p> <p>24 life-altering complication wouldn't count as</p>	<p>1 just totally different?</p> <p>2 A. They're -- there's side effects and there's</p> <p>3 injuries.</p> <p>4 Q. Okay.</p> <p>5 A. And the side effect has more to do with what</p> <p>6 pertains to one particular product and an injury could</p> <p>7 be from anything that is used in surgery.</p> <p>8 Q. Do you consider a permanent injury a severe</p> <p>9 injury?</p> <p>10 MR. SNELL: Form, incomplete hypothetical.</p> <p>11 A. I apologize for that.</p> <p>12 Can you please repeat that?</p> <p>13 (The requested portion of the record was</p> <p>14 read back by the reporter.)</p> <p>15 A. There could be permanent effects of surgery</p> <p>16 that are not necessarily severe and severe that are</p> <p>17 not exactly permanent.</p> <p>18 Q. (By Mr. De La Cerda) Do you consider a</p> <p>19 risk or complication that requires additional</p> <p>20 surgeries a severe side effect?</p> <p>21 A. Based on the -- on the -- on the evidence on</p> <p>22 which -- which has a classification is not considered</p> <p>23 severe, is not considered severe if he needs just to</p> <p>24 go back to the operating room.</p>
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<p>1 evidence under the framework that you're using;</p> <p>2 right?</p> <p>3 A. The -- the findings, whatever findings, that</p> <p>4 being from a physician, that being from a patient,</p> <p>5 that being from -- from a manufacturer or anybody</p> <p>6 else, a group -- whatever findings needs to be</p> <p>7 corroborated by evidence, that's why we have studies,</p> <p>8 that's why we have a well-placed methodology for</p> <p>9 evidence.</p> <p>10 Q. And so the medical -- well, the studies are</p> <p>11 going to be the foundation of that evidence, not some</p> <p>12 information from the manufacturer; right?</p> <p>13 A. Any -- any -- any radical information, that</p> <p>14 being of things being too good or too bad need to be</p> <p>15 evaluated on the light of a randomized control trial,</p> <p>16 needs to be evaluated on if there is no randomized</p> <p>17 control trial, needs to be evaluated based on the type</p> <p>18 of the study that we have and the clinical experience.</p> <p>19 Q. Do you consider a permanent injury a severe</p> <p>20 side effect?</p> <p>21 A. A permanent injury is different from a side</p> <p>22 effect.</p> <p>23 Q. Okay. So what -- so you don't believe that</p> <p>24 a permanent injury is a severe side effect or they're</p>	<p>1 Q. So that's not severe in your eyes.</p> <p>2 A. Yeah.</p> <p>3 Q. Do you consider risk or complication that</p> <p>4 seriously alters a patient's quality of life a severe</p> <p>5 side effect?</p> <p>6 A. It could be -- that side effect could be for</p> <p>7 improvement of a quality of life, that could be --</p> <p>8 that's an effect on the side or a side effect, the way</p> <p>9 we usually recognize it, can be deteriorating to the</p> <p>10 quality of life. I will have to look at the specific</p> <p>11 situation and look at the specific data on it.</p> <p>12 Q. Okay. Let's shift gears. The content and</p> <p>13 substance of the professional education sponsored by</p> <p>14 Ethicon on it's TVT, TVT-O, Gynemesh, Prolift and</p> <p>15 Prosima did not and does not contradict the content</p> <p>16 and substance of the IFUs for these products; correct?</p> <p>17 MR. SNELL: Form, overbroad.</p> <p>18 A. The content of the -- of these programs use</p> <p>19 the IFU.</p> <p>20 Q. (By Mr. De La Cerda) They don't</p> <p>21 contradict it; right?</p> <p>22 A. No, there is -- there is actually -- in the</p> <p>23 presentations that you're going to see, they -- they</p> <p>24 work -- they work together.</p>

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<p style="text-align: right;">Page 122</p> <p>1 Q. Okay. Now, I figured the most efficient way</p> <p>2 to do this, because now we'll get into the substance</p> <p>3 of the various issues that you've opined on, there are</p> <p>4 many of these issues that can be grouped together as</p> <p>5 to all the products and I think that will be the</p> <p>6 fastest way to get through it, so that's what I'm</p> <p>7 going to do.</p> <p>8 So, for example, I'm about to ask you about</p> <p>9 the IFU. I'm going to ask you about -- these are</p> <p>10 general questions about the IFUs of the TVT, TVT-O,</p> <p>11 Gynemesh, Prolift and Prosima. I think we can do it</p> <p>12 all at once.</p> <p>13 A. Yes.</p> <p>14 Q. First of all, are you familiar with the</p> <p>15 contents of the various versions of the IFUs for the</p> <p>16 TVT, TVT-O, Gynemesh, Prolift and Prosima?</p> <p>17 A. I'm aware that they're -- they have changed</p> <p>18 in 2015.</p> <p>19 Q. And you're generally aware of the contents,</p> <p>20 right, of those -- of those various IFUs?</p> <p>21 A. Yes, there are IFUs that actually might be</p> <p>22 able to tell you separate steps.</p> <p>23 Q. Okay. Do you intend to offer an opinion as</p> <p>24 to whether the warnings in the IFUs for the TVT,</p>	<p style="text-align: right;">Page 124</p> <p>1 there, what adverse reactions would go in there, and</p> <p>2 what procedure steps would go in there? Do you know</p> <p>3 if there's any written standards that Ethicon relied</p> <p>4 on?</p> <p>5 A. I'm -- I'm aware of that. As for many</p> <p>6 products, they -- the ones that are disclosed are the</p> <p>7 ones that are specific to that product.</p> <p>8 Q. Okay.</p> <p>9 A. In other words, they're not comprehensive</p> <p>10 guides on incontinence or -- or prolapse care.</p> <p>11 Q. Okay. Have you ever, in your career, been</p> <p>12 involved in writing or preparing an IFU for a medical</p> <p>13 device?</p> <p>14 A. I have not written an IFU. I read -- I read</p> <p>15 IFUs through most of my career.</p> <p>16 Q. Have you ever studied the question of what</p> <p>17 risks and complications were known to doctors across</p> <p>18 the country with various background and levels of</p> <p>19 experience with regard to the use of the TVT, TVT-O,</p> <p>20 Gynemesh, Prolift and Prosima? Did you ever study</p> <p>21 that question?</p> <p>22 A. The risk with mesh were, with these</p> <p>23 procedures in general, were addressed in a variety of</p> <p>24 ways. And those were -- there were communications</p>
<p style="text-align: right;">Page 123</p> <p>1 TVT-O, Gynemesh, Prolift and Prosima were sufficient</p> <p>2 to apprise doctors of the risks of those products?</p> <p>3 A. Yes, I will -- I will give an opinion on</p> <p>4 that.</p> <p>5 Q. And your opinion will be that they were</p> <p>6 sufficient warnings; right?</p> <p>7 A. Yes, that will be my opinion.</p> <p>8 Q. Do you know what standards Ethicon applied</p> <p>9 in terms of what needed to be included in the warnings</p> <p>10 in the IFUs for the TVT, TVT-O, Gynemesh, Prolift and</p> <p>11 Prosima?</p> <p>12 A. That's the standards apply?</p> <p>13 Q. Yes.</p> <p>14 A. I'm aware of certain standards that were</p> <p>15 used for the IFU.</p> <p>16 Q. Okay. And what were those?</p> <p>17 A. The area on side effects, on warnings,</p> <p>18 procedure steps, and the specifics on informing about</p> <p>19 the need for specialized training to perform these</p> <p>20 procedures.</p> <p>21 Q. Do you know what -- do you know whether</p> <p>22 there's any -- are there specific, like, written</p> <p>23 standards, though, that you're aware of that Ethicon</p> <p>24 used in deciding exactly what warnings would go in</p>	<p style="text-align: right;">Page 125</p> <p>1 from the American College of OB/GYN, there were</p> <p>2 meetings that -- there were journals, there were so</p> <p>3 many different -- different venues that we have grown</p> <p>4 used to read and understand.</p> <p>5 The IFU, we -- we all expected that it was</p> <p>6 going to give us one specific set, but the other set</p> <p>7 on the evidence, we expected that from our -- our</p> <p>8 scientific data.</p> <p>9 Q. So back to the question, though: Did you</p> <p>10 ever study -- ever perform a study or ever study or do</p> <p>11 questionnaires that determine what doctors actually</p> <p>12 knew about these products, about the risks and</p> <p>13 complications of those products? Did you ever perform</p> <p>14 a study like that?</p> <p>15 A. There was -- to my -- to my knowledge,</p> <p>16 there's no -- not a study that have address -- address</p> <p>17 it.</p> <p>18 Q. And you, personally, haven't done a study</p> <p>19 either; right?</p> <p>20 A. No, I have not done -- done a study. I have</p> <p>21 examined forms on evaluation of surgical skills that</p> <p>22 at one time I use.</p> <p>23 Q. Okay. But on this specific question, you</p> <p>24 haven't actually performed a specific study looking at</p>

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<p>1 what doctors actually knew about the risks and</p> <p>2 complications associated with transvaginal mesh</p> <p>3 products?</p> <p>4 A. I have not performed such study.</p> <p>5 Q. Do you agree that a surgeon should be able</p> <p>6 to solely rely on the warnings and description of risk</p> <p>7 and complications in the IFUs for the TVT, TVT-O,</p> <p>8 Gynemesh, Prolift and Prosima?</p> <p>9 MR. SNELL: Form, incomplete.</p> <p>10 A. We -- we don't rely just on the IFU.</p> <p>11 Q. (By Mr. De La Cerda) Do you agree that a</p> <p>12 surgeon should be able to just rely on the IFU or do</p> <p>13 you disagree?</p> <p>14 MR. SNELL: Same objection, asked and</p> <p>15 answered.</p> <p>16 A. I -- I disagree that a surgeon should be --</p> <p>17 rely just on the IFU.</p> <p>18 Q. (By Mr. De La Cerda) Should the IFUs for</p> <p>19 the TVT, TVT-O, Gynemesh, Prolift and Prosima</p> <p>20 include the frequency, duration and severity of</p> <p>21 risks associated with those devices?</p> <p>22 MR. SNELL: Same objection, lacks</p> <p>23 foundation.</p> <p>24 A. No. As complete as an IFU could be, as</p>	<p>1 Q. (By Mr. De La Cerda) So is that a no?</p> <p>2 A. No, that's not necessarily a no. Actually,</p> <p>3 that's -- that's exactly -- the IFU cannot -- cannot</p> <p>4 be a comprehensive guide.</p> <p>5 Q. So what -- what characteristics of these</p> <p>6 products -- strike that.</p> <p>7 Do you believe that the IFUs for the TVT,</p> <p>8 TVT-O, Gynemesh, Prolift and Prosima sufficiently</p> <p>9 address any characteristics of those products that</p> <p>10 could significantly increase their risk of severe</p> <p>11 complication?</p> <p>12 MR. SNELL: Objection.</p> <p>13 A. As it pertains to the product, yes.</p> <p>14 Q. (By Mr. De La Cerda) The information in</p> <p>15 the IFUs for the TVT, TVT-O, Gynemesh, Prolift and</p> <p>16 Prosima should be truthful; correct?</p> <p>17 A. Yes.</p> <p>18 Q. The information in the IFUs for the TVT,</p> <p>19 TVT-O, Gynemesh, Prolift and Prosima should be</p> <p>20 accurate; correct?</p> <p>21 A. Yes.</p> <p>22 Q. The information in the IFUs for the TVT,</p> <p>23 TVT-O, Gynemesh, Prolift and Prosima should be</p> <p>24 complete; correct?</p>
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<p>1 complete as an IFU may want to be, it would not be</p> <p>2 able to address all of them. It may comply with what</p> <p>3 we expect from the IFU, but it will not be able to</p> <p>4 address every single -- every single risk that has to</p> <p>5 do with a surgery that is much more complicated than</p> <p>6 what an IFU can address.</p> <p>7 Q. (By Mr. De La Cerda) The IFUs for the TVT</p> <p>8 TVT-O, Gynemesh, Prolift and Prosima should include</p> <p>9 all known material risks associated with these</p> <p>10 products; right?</p> <p>11 MR. SNELL: Form, asked and answered.</p> <p>12 A. It should -- it should include all -- all</p> <p>13 unknown risks about the material, but not necessarily</p> <p>14 will address all known material risk.</p> <p>15 Q. (By Mr. De La Cerda) The IFUs for the</p> <p>16 TVT, TVT-O, Gynemesh, Prolift and Prosima should</p> <p>17 include all characteristics of these products that</p> <p>18 can significantly increase the risk of severe</p> <p>19 complications; right?</p> <p>20 MR. SNELL: Object to form, lacks</p> <p>21 foundation. This was asked and answered earlier.</p> <p>22 A. Is the -- the instructions for use for the</p> <p>23 device, it addresses one area. The -- the rest is</p> <p>24 based on the data.</p>	<p>1 MR. SNELL: Objection, form. Prior</p> <p>2 testimony.</p> <p>3 A. It is complete -- it is complete for the</p> <p>4 product. That's my -- my opinion.</p> <p>5 Q. (By Mr. De La Cerda) The information in</p> <p>6 the IFUs for the TVT, TVT-O, Gynemesh, Prolift and</p> <p>7 Prosima should be fair and balanced about the risks</p> <p>8 and benefits of these products?</p> <p>9 MR. SNELL: Same objection.</p> <p>10 A. It -- it should be fair and balanced for</p> <p>11 what pertains to the product.</p> <p>12 Q. (By Mr. De La Cerda) Once an IFU is out</p> <p>13 there and -- for physicians to review, if Ethicon</p> <p>14 learned of a risk or complication that was not</p> <p>15 previously warned about in the IFU and it was a</p> <p>16 significant risk or complication in terms of the</p> <p>17 harm it caused to women, do you know whether or not</p> <p>18 Ethicon had an obligation to get that information in</p> <p>19 the IFU?</p> <p>20 MR. SNELL: Objection, hypothetical, legal</p> <p>21 standard.</p> <p>22 A. As long as it's evidence-based, yes.</p> <p>23 Q. (By Mr. De La Cerda) Have you compared</p> <p>24 the differences between the IFUs for the TVT, TVT-O,</p>

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<p>1 Gynemesh, Prolift and Prosima, are you aware of the</p> <p>2 differences between them?</p> <p>3 A. I have -- I have read those -- read those --</p> <p>4 and I have read them many times and I have use it to</p> <p>5 explain the procedure.</p> <p>6 Q. And so you've seen that over time there's</p> <p>7 been some updates to the IFUs; right?</p> <p>8 A. Yes, I have seen that.</p> <p>9 Q. Is there a single long-term randomized</p> <p>10 control trial for TVT, TVT-O, Gynemesh, Prolift or</p> <p>11 Prosima with safety as a primary end point?</p> <p>12 A. I -- I -- they don't -- they're not all</p> <p>13 included. There is a randomized control trial that</p> <p>14 explains about safety of Gynemesh, there is a</p> <p>15 randomized control trial that explains for Prolift.</p> <p>16 For each one of them, there's -- safety have</p> <p>17 been included. Not only have those randomized control</p> <p>18 trials explain about safety, they have -- it has</p> <p>19 spoken specifically about the percentage and the</p> <p>20 clinical significance of each one of the</p> <p>21 complications.</p> <p>22 Q. Are any of the studies that you're</p> <p>23 referencing there, has the primary end point, though,</p> <p>24 been safety in the study?</p>	<p>1 Gynemesh on -- or safety of Marlex in the use -- use</p> <p>2 on -- for cystocele repair.</p> <p>3 There's -- there are multiple studies -- I</p> <p>4 can go on with the list -- that cites safety as one of</p> <p>5 the -- of the things that they study.</p> <p>6 Q. So the point of this -- by the way, this is</p> <p>7 not my question. I never -- this question, to me,</p> <p>8 never really gets me anywhere.</p> <p>9 But the point is that all the studies that</p> <p>10 have been done on any of these mesh products, the</p> <p>11 number one end point is, is it effective; right? Is</p> <p>12 it effective and then, by the way, was it safe, too?</p> <p>13 None of these studies is like number one</p> <p>14 thing safety; right?</p> <p>15 MR. SNELL: Objection, overbroad.</p> <p>16 A. The -- there's even a better level of</p> <p>17 evidence that speaks about safety and is when you</p> <p>18 compare the use of any of these products with what</p> <p>19 has -- with the -- with the safety profile when you</p> <p>20 don't use the product. And that's where the</p> <p>21 randomized control trial comes into -- into play.</p> <p>22 The randomized control trials has the</p> <p>23 capability of evaluating something that I have use</p> <p>24 without mesh and compare it with something with mesh.</p>
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<p>1 A. The safety -- the safety was evaluated on --</p> <p>2 on Gynemesh.</p> <p>3 Q. Do you know what the name of that study was?</p> <p>4 A. Yes, yes.</p> <p>5 Q. There is another one over here too.</p> <p>6 A. Gynemesh. Gynemesh on the -- okay. So --</p> <p>7 so on the -- to begin with the mesh, we have the</p> <p>8 Flood, F-l-o-o-d, paper on the use of Marlex.</p> <p>9 Q. And what does that study show?</p> <p>10 A. That's for the anterior colporrhaphy</p> <p>11 reinforced with Marlex mesh for treatment of</p> <p>12 cystocele.</p> <p>13 Q. Is this one of the studies that shows it has</p> <p>14 a primary end point of safety?</p> <p>15 A. It's not titled "safety," but they -- they</p> <p>16 conclude on that study that this is safe to use. And</p> <p>17 then there's Nicita, Giulia.</p> <p>18 Q. How do you spell that?</p> <p>19 A. Giulia Nicita, N-i-c-i-t-a.</p> <p>20 Q. And what is that study?</p> <p>21 A. And it shows exactly applications in terms</p> <p>22 of they were able to save -- to do it with safety.</p> <p>23 So to be accurate to the response to your</p> <p>24 question, there's no study that says safety of</p>	<p>1 And that has been used -- that has been reported for</p> <p>2 Gynemesh, it has been reported for Prolift, it has</p> <p>3 been -- was reported for -- for TVT and TVT-O, and it</p> <p>4 was so -- so consistently demonstrated that when it</p> <p>5 came to Prosima, it became a cohort study.</p> <p>6 Q. (By Mr. De La Cerda) Is it -- is it your</p> <p>7 opinion that the studies show that any time that</p> <p>8 mesh products have been compared to whatever the</p> <p>9 alternative was, a non-mesh alternative, that the</p> <p>10 mesh products have been shown to be safer than the</p> <p>11 non-mesh alternative?</p> <p>12 A. It's -- it has been shown not to have</p> <p>13 statistically significantly increased in the number of</p> <p>14 complications or the frequency of these complications.</p> <p>15 Q. Right. But that's a good point. So it's</p> <p>16 been shown to be as safe; right? And really, the</p> <p>17 differentiating factor is whether it's more effective;</p> <p>18 is that fair?</p> <p>19 A. It has been shown to be as safe and in some</p> <p>20 situations, it has been shown -- it has shown to be</p> <p>21 even safer.</p> <p>22 Take, for example, the use in the initial</p> <p>23 study of Marcus Carey on mesh, on Prosima, and</p> <p>24 straight -- and the known use of an implant.</p>

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<p>1 When you compare, you see that the three</p> <p>2 patients that he had to operate for vaginal stenosis</p> <p>3 were the ones that did not have a mesh. So there you</p> <p>4 have an instance in which there was more complications</p> <p>5 with -- by not using mesh than by using the mesh.</p> <p>6 Is that directly related to the mesh? And</p> <p>7 that's something that could be addressed with a</p> <p>8 randomized control trial.</p> <p>9 When we do sutures, suture repairs, and we</p> <p>10 call them "native tissue repairs," in a randomized</p> <p>11 control trial or even when we do a cohort of sutures,</p> <p>12 we see complications on sutures in 36% of uterosacral</p> <p>13 ligament suspension, we see suture complications in</p> <p>14 sacrospinous ligament fixations, and when they're</p> <p>15 compared with mesh, there is -- there is much less.</p> <p>16 Q. So on the issue of whether -- you know, the</p> <p>17 FDA came out with an opinion about -- they actually</p> <p>18 described that repairs with pelvic organ prolapse mesh</p> <p>19 are no more effective and might be more dangerous than</p> <p>20 the alternative non-mesh repairs; right?</p> <p>21 MR. SNELL: Objection to foundation.</p> <p>22 A. That -- that was the -- that was an opinion</p> <p>23 that they came in, in the small panel, analyzing the</p> <p>24 data, I don't know, for two, three days, but that's</p>	<p>1 Q. You're aware that Ethicon had evidence as</p> <p>2 early as 2006 that after elongation, mechanically cut</p> <p>3 mesh has a greater tendency than laser cut mesh to</p> <p>4 degrade, lose particles, lose structure, rope, fray</p> <p>5 and curl; right?</p> <p>6 MR. SNELL: Form. Form, foundation.</p> <p>7 Go ahead.</p> <p>8 A. What -- what I saw in a picture was an</p> <p>9 uniaxial test done in a sling beyond the capabilities</p> <p>10 of a sling and beyond any forces that could be placed</p> <p>11 on a sling when used properly.</p> <p>12 Q. (By Mr. De La Cerda) But you also saw in</p> <p>13 those pictures that at least under those</p> <p>14 circumstances, the mechanically cut mesh as compared</p> <p>15 to the laser cut mesh had a tendency to lose</p> <p>16 particles, lose structure, rope, fray and curl;</p> <p>17 correct?</p> <p>18 A. They -- they show particles that we -- we</p> <p>19 have seen over -- over time, not only on that, but</p> <p>20 also in sutures. They -- in a picture, I saw a</p> <p>21 picture of it, and I saw the pictures of uniaxial</p> <p>22 testing and I saw the communications about it, but</p> <p>23 that's as much as I can say, I saw it.</p> <p>24 Q. And you know that that information was in</p>
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<p>1 not -- I don't know for how many days they analyze it.</p> <p>2 I don't even know what papers they consider.</p> <p>3 But the preponderance of the evidence in the</p> <p>4 randomized control trial is that it's not more</p> <p>5 dangerous.</p> <p>6 Q. (By Mr. De La Cerda) Okay. So on that</p> <p>7 particular -- I'm sorry.</p> <p>8 A. I apologize. I'll just turn it off.</p> <p>9 Q. So on that particular issue, you disagree</p> <p>10 with the FDA; right?</p> <p>11 MR. SNELL: Form, foundation.</p> <p>12 I think that's misleading because there's</p> <p>13 two different time periods, Counsel.</p> <p>14 A. I -- I disagree -- I disagree with -- with</p> <p>15 the FDA opinion based on everything else that I review</p> <p>16 and that I present on my report.</p> <p>17 Q. (By Mr. De La Cerda) All right. Let's</p> <p>18 shift gears a little bit and talk some about this is</p> <p>19 a TVT and TVT-O issue.</p> <p>20 You're aware that the TVT and the TVT-O can</p> <p>21 either be mechanically cut into its sling shape or</p> <p>22 laser cut into its sling shape; right?</p> <p>23 A. It can -- the edges can be mechanically cut</p> <p>24 or laser cut or personally cut.</p>	<p>1 the files of Ethicon at least as of 2006; right?</p> <p>2 A. I -- I don't know the time when the</p> <p>3 information was.</p> <p>4 Q. Have you personally seen a TVT or TVT-O that</p> <p>5 has lost particles, lost structure, roped, frayed or</p> <p>6 curled in your practice?</p> <p>7 A. The only time that I have seen it stretch</p> <p>8 like that is when I'm actually -- one that I was</p> <p>9 removing that I put a lot of force into it. That's --</p> <p>10 that's a way much force that any patient could ever</p> <p>11 generate with a sneeze or cough.</p> <p>12 Q. You mentioned the one patient that you had</p> <p>13 that you're removing the sling where it's too tight?</p> <p>14 A. Right.</p> <p>15 Q. Is this the person you were talking about?</p> <p>16 A. That might be the same person; I cannot tell</p> <p>17 you with certainty.</p> <p>18 Q. So when the mesh was placed too tightly, you</p> <p>19 saw -- would you call that roping or what was it that</p> <p>20 you actually saw?</p> <p>21 A. I -- I -- I started dissecting it and I saw</p> <p>22 that she still had some -- and the only way I can -- I</p> <p>23 can recall it is because I actually saw those pictures</p> <p>24 yesterday in one of the -- of the slide sets.</p>

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<p>1 And all I could -- all I could see was that</p> <p>2 I actually had to -- had to pull on it from inside,</p> <p>3 normal attachment. This was not roped, this was not</p> <p>4 curled, this not -- there's no such thing that I could</p> <p>5 describe in telling in general terms or in scientific</p> <p>6 terms. I -- this was one -- one anecdotal case in</p> <p>7 which I -- that's the only one that looks like the</p> <p>8 dimensions stretch -- stretch on that device.</p> <p>9 Q. So would your testimony be that you've never</p> <p>10 seen a TVT or TVT-O mechanically cut, lose particles,</p> <p>11 lose structure, rope, fray or curl in your own</p> <p>12 practice?</p> <p>13 A. No, because it has a plastic sheath.</p> <p>14 Q. So you've never seen that yourself?</p> <p>15 A. No.</p> <p>16 Q. Should the mechanically cuts -- strike that.</p> <p>17 Excuse me.</p> <p>18 Should mechanically cut meshes tendency</p> <p>19 to -- in comparison to laser cut mesh -- so should</p> <p>20 that tendency to degrade, lose particles, lose</p> <p>21 structure, rope, fray or curl be included in the IFU</p> <p>22 for the TVT and TVT-O or no?</p> <p>23 MR. SNELL: Objection, foundation.</p> <p>24 A. I don't find a need to include that because</p>	<p>1 within groups that are well-respected within my</p> <p>2 specialty, that have not describe, not in a single</p> <p>3 time, not in any of these papers, that there is such a</p> <p>4 thing happening.</p> <p>5 Q. If mechanically cut mesh's tendency in</p> <p>6 comparison to laser cut mesh to degrade, lose</p> <p>7 particles, lose structure, rope, fray and curl is</p> <p>8 clinically significant or clinically relevant, should</p> <p>9 it be included in the IFU for the TVT and TVT-O?</p> <p>10 A. It --</p> <p>11 MR. SNELL: Objection. Hold on, give me a</p> <p>12 minute.</p> <p>13 Objection, improper hypothetical based on</p> <p>14 the particle.</p> <p>15 A. It would have -- it would have to be</p> <p>16 reported. It would have to be reported by</p> <p>17 something -- by something dependent by randomized</p> <p>18 control trial.</p> <p>19 If -- any attributes that being on any of</p> <p>20 the polar sides of things -- things working at one</p> <p>21 level or another in both sides of the spectrum needs</p> <p>22 to be validated by scientific testing.</p> <p>23 Q. (By Mr. De La Cerda) This is a question</p> <p>24 that I'll have throughout several of these opinions.</p>
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<p>1 that's something that has not been demonstrated</p> <p>2 consistently.</p> <p>3 Q. (By Mr. De La Cerda) Is that -- is that</p> <p>4 your basis for that opinion or are there</p> <p>5 additional -- is there additional information that</p> <p>6 provides a basis for that opinion?</p> <p>7 A. I have not seen any scientific evidence that</p> <p>8 the mesh curls or ropes or -- or -- or frays. Nothing</p> <p>9 that I can -- I can tell you that, okay, this is --</p> <p>10 we -- we saw this observation on this patient and we</p> <p>11 have reported it consistently or out of this number of</p> <p>12 procedures that we did, this number actually showed</p> <p>13 that. And if it happened, what is -- how does that</p> <p>14 translate into the clinical -- and I keep talking with</p> <p>15 my hands because -- that will never get into the</p> <p>16 deposition, but the -- on the -- I have not seen that</p> <p>17 be reported or how that can translate into clinical --</p> <p>18 into clinical behavior.</p> <p>19 Q. So on this issue, the basis for your opinion</p> <p>20 is really the absence of information supporting this</p> <p>21 information should be in the IFU; right?</p> <p>22 A. And the fact that there are multiple</p> <p>23 randomized control trials well -- well-designed</p> <p>24 control trials, surgical trials by good surgeons</p>	<p>1 I want to make sure to say it in a way that you</p> <p>2 would agree with, because I want you to define for</p> <p>3 me what it would require for this information to</p> <p>4 suddenly be required to be in the IFU.</p> <p>5 And so what -- what would be required from</p> <p>6 your perspective for the information about the</p> <p>7 differences between a mechanically cut and laser cut</p> <p>8 mesh on the issue of degradation, loss of particles,</p> <p>9 loss of structure, roping, fraying, curling, what</p> <p>10 would it take for that information to suddenly be</p> <p>11 information that needs to be in the IFU?</p> <p>12 MR. SNELL: Objection, same objection as</p> <p>13 before.</p> <p>14 A. To make it to the -- to the IFU, needs to be</p> <p>15 something that is independent of -- of just -- just</p> <p>16 the technique beyond what's described in the IFU. If</p> <p>17 you see something like a device or a suture breaking,</p> <p>18 it needs -- the IFU should say, do not make it so</p> <p>19 tight or place a spacer under the urethra in the case</p> <p>20 of slings. The IFU says that.</p> <p>21 So -- so -- and the insertion of the needle</p> <p>22 or the removal of the plastic sheath is being done,</p> <p>23 there needs to be instructions in the IFU for the</p> <p>24 appropriate placement. So this -- this is not about</p>

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<p>1 saying this mesh curls or ropes or -- that's not --</p> <p>2 that's not what the -- what I expect from IFU. What I</p> <p>3 expect is give me the proper technique so I don't put</p> <p>4 this material to this extremes that would cause it to</p> <p>5 behave this way.</p> <p>6 Q. (By Mr. De La Cerda) So I understand</p> <p>7 the -- first it would need to be independent of the</p> <p>8 technique, but if the roping, fraying, curling, loss</p> <p>9 of structure, if it's clinically relevant and</p> <p>10 statistically significant, that would need to be in</p> <p>11 the IFU; right?</p> <p>12 MR. SNELL: Objection, improper</p> <p>13 hypothetical, vague.</p> <p>14 A. And to the -- and to the level that it would</p> <p>15 say, okay, this is -- this is how it happens in the</p> <p>16 clinical setting, not just in a machine.</p> <p>17 Q. (By Mr. De La Cerda) And I guess that</p> <p>18 would be encompassed though -- I mean, if it's</p> <p>19 statistically significant through randomized control</p> <p>20 trials -- let me think about that. So it would need</p> <p>21 to be shown through randomized control trials that</p> <p>22 actually involve human implants, not just benched-up</p> <p>23 testing or whatever it is in the lab; right?</p> <p>24 A. If you blind -- if you blind this study in a</p>	<p>1 performed a study comparing mechanically cut mesh</p> <p>2 versus laser cut mesh in -- actually in women; right?</p> <p>3 A. It's --</p> <p>4 MR. SNELL: Foundation.</p> <p>5 Go ahead.</p> <p>6 A. It's -- I'm not aware of any study that was</p> <p>7 performed like that, in that model.</p> <p>8 Q. (By Mr. De La Cerda) If mechanically cut</p> <p>9 mesh, TVT or TVT-O, loses particles when its</p> <p>10 implanted in a woman, is there potential for those</p> <p>11 lost particles to migrate into the woman's vaginal</p> <p>12 wall and cause pain?</p> <p>13 A. That's a hypothesis. It has never been</p> <p>14 demonstrated.</p> <p>15 Q. Do you know if it's possible or no?</p> <p>16 A. It's medically -- it's medically --</p> <p>17 medically possible, which is way below that within</p> <p>18 the -- within the settings of certain medical</p> <p>19 probability.</p> <p>20 Q. Okay. Still on this mechanically cut versus</p> <p>21 laser cut issue. You agree that mesh -- that mesh and</p> <p>22 polypropylene slings that is too stiff or rigid can</p> <p>23 increase the risk of complications like erosion,</p> <p>24 voiding dysfunction, and urethral obstruction; right?</p>
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<p>1 way that physicians don't know which type of mesh</p> <p>2 they're -- they're using, you could -- that would be a</p> <p>3 good start.</p> <p>4 Q. Okay. Do you know if Ethicon ever performed</p> <p>5 a test like that, where they compared laser cut mesh</p> <p>6 versus mechanically cut mesh actually implanted in</p> <p>7 women?</p> <p>8 A. I -- I don't see anyone placing any human</p> <p>9 through the stress that a machine could do -- could do</p> <p>10 that.</p> <p>11 Q. But Ethicon never performed a study like</p> <p>12 that; right?</p> <p>13 A. I'm going to give you a better -- that was a</p> <p>14 very unclear answer what I just gave you.</p> <p>15 I don't see -- I don't see an implant being</p> <p>16 stressed to the forces that could be done in uniaxial</p> <p>17 testing. Uniaxial testing doesn't always translate</p> <p>18 into the behavior in the human body.</p> <p>19 The IFU was good in addressing the area that</p> <p>20 was most important on the urethra and the design was</p> <p>21 good in addressing the placement and the -- and the</p> <p>22 confirmation of the mesh with the minimum of the</p> <p>23 formation.</p> <p>24 Q. But back to the question. Ethicon never</p>	<p>1 MR. SNELL: Form.</p> <p>2 A. No -- no study has been able to corroborate</p> <p>3 that.</p> <p>4 Q. (By Mr. De La Cerda) So would you</p> <p>5 disagree with that statement?</p> <p>6 A. I -- I would disagree to that statement</p> <p>7 based on the fact that there's no evidence confirming</p> <p>8 it.</p> <p>9 Q. You know that in 2004, Ethicon tested laser</p> <p>10 cut mesh and found it to be more rigid or stiffer than</p> <p>11 mechanically cut mesh; right?</p> <p>12 A. Regardless of the findings that Ethicon may</p> <p>13 have found, I'm not aware that they found one way or</p> <p>14 the other, and with all the research, it would not</p> <p>15 surprise me that they may have found one way or the</p> <p>16 other. The question is if that has any -- any</p> <p>17 translation to clinical symptoms and the ans- -- of</p> <p>18 the ones you described, and my answer to that is no</p> <p>19 evidence of it.</p> <p>20 Q. Okay. So that leads to the next question</p> <p>21 and this is a question I'm going to have with all</p> <p>22 these opinions, but should laser cut mesh's greater</p> <p>23 stiffness or rigidity in comparison to mechanically</p> <p>24 cut mesh be included in the IFUs for the TVT and</p>

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<p>1 TVT-O?</p> <p>2 MR. SNELL: Objection, lacks foundation.</p> <p>3 A. No -- no -- there's no evidence that it</p> <p>4 could work one way or the other. Why would they</p> <p>5 include it in the IFU?</p> <p>6 Q. (By Mr. De La Cerda) Okay. So let's talk</p> <p>7 about the bases for why it doesn't need to be</p> <p>8 included in the IFU. What is your basis for that?</p> <p>9 A. It's a -- the use of a laser cut or</p> <p>10 mechanical cut meshes do not translate into your</p> <p>11 procedure being performed any differently and they --</p> <p>12 with laser cut or without or with mechanical cut, what</p> <p>13 you need to be aware is not to place a sling under</p> <p>14 excessive tension, which is something that we have</p> <p>15 learned even before there was mesh, not to place a</p> <p>16 sling under excessive tension, follow good surgical</p> <p>17 principles. And if there was any question about that,</p> <p>18 then doctors could have -- could have requested to be</p> <p>19 trained on it, but I would not include something on</p> <p>20 the IFU that would just confuse the issue on how to --</p> <p>21 how to perform the procedure.</p> <p>22 Q. Okay. If laser cut mesh has greater</p> <p>23 stiffness or rigidity in comparison to mechanically</p> <p>24 cut mesh, is clinically relative and statistically</p>	<p>1 A. Yes.</p> <p>2 Q. And you're aware that Nilsson and Falconer</p> <p>3 opposed the use of laser cut mesh because it did not</p> <p>4 have the same stretch profile of mechanically cut</p> <p>5 mesh. Are you aware of that?</p> <p>6 MR. SNELL: Form.</p> <p>7 Go ahead.</p> <p>8 A. I am not aware of their internal</p> <p>9 conversations about it.</p> <p>10 Q. (By Mr. De La Cerda) And does that have</p> <p>11 any effect on your opinion one way or the other?</p> <p>12 A. It doesn't. Whatever -- whatever</p> <p>13 interaction they had, I would consider just a healthy</p> <p>14 scientific exercise, but until there's data supporting</p> <p>15 its use and there's data showing that there is a</p> <p>16 difference in performance, there is no need to make a</p> <p>17 difference -- to make a different recommendation.</p> <p>18 Q. What is the proper way to tension the TVT</p> <p>19 device?</p> <p>20 A. It's -- it's to do it tension-free and</p> <p>21 tension-free means that there is preservation of the</p> <p>22 width of the sling up to 75 percent.</p> <p>23 Q. I think I missed something. What did you</p> <p>24 mean -- can you explain that again?</p>
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<p>1 significant, should it be included in the IFUs for the</p> <p>2 TVT and TVT-O?</p> <p>3 MR. SNELL: Objection, lacks foundation,</p> <p>4 improper hypothetical.</p> <p>5 A. There's -- there's no correlate it</p> <p>6 clinically. So my answer to that is no, I would not</p> <p>7 expect them to write in the IFU.</p> <p>8 Q. (By Mr. De La Cerda) So this is a</p> <p>9 hypothetical. I'm saying assume that it's</p> <p>10 discovered to be clinically relevant and</p> <p>11 statistically significant, under those circumstances</p> <p>12 would it then be proper to put it in the IFU?</p> <p>13 MR. SNELL: Same objection.</p> <p>14 A. If it's clinically -- clinically relevant or</p> <p>15 statistically significant, then it may have been</p> <p>16 included on the IFU if it pertains to the performance</p> <p>17 of the procedure.</p> <p>18 Q. (By Mr. De La Cerda) Now, you're aware</p> <p>19 that -- you know Ulmsten is the original -- one of</p> <p>20 the original inventors of the TVT; right?</p> <p>21 A. Yes.</p> <p>22 Q. You know a couple of the guys that studied</p> <p>23 TVT with him were Nilsson and Falconer, you remember</p> <p>24 those names being mentioned in the studies?</p>	<p>1 A. By the time that I finish doing my</p> <p>2 procedure, the width on my TVT needs to be at least</p> <p>3 1.1 -- at least 75 percent of 1.1-centimeter, that's</p> <p>4 not just with TVT --</p> <p>5 Q. Okay.</p> <p>6 A. -- that's with any sling that I may place.</p> <p>7 Q. Where is that information in the IFU?</p> <p>8 A. That's not going to be in the IFU because</p> <p>9 that's an observation of Jaime Sepulveda.</p> <p>10 Q. Do you believe that Ethicon is responsible</p> <p>11 to tell physicians how to properly tension the TVT?</p> <p>12 A. There's -- there's -- there's information on</p> <p>13 the IFU about not overtensioning.</p> <p>14 Q. There's information about that, but is there</p> <p>15 information, like an exact measurement on how to</p> <p>16 tension? For example, I liked your example of</p> <p>17 75 percent of 1.1 centimeters.</p> <p>18 Does Ethicon have a responsibility to</p> <p>19 communicate to physicians an exact way in tensioning</p> <p>20 the TVT?</p> <p>21 MR. SNELL: Form.</p> <p>22 A. I think that Ethicon make every possible</p> <p>23 effort through their -- through their education</p> <p>24 programs to -- to emphasize good practices in doing a</p>

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<p style="text-align: right;">Page 150</p> <p>1 sling. Ethicon is not re-inventing our technique to</p> <p>2 do a continence procedure.</p> <p>3 Q. (By Mr. De La Cerda) When you taught on</p> <p>4 behalf of Ethicon regarding slings, did you discuss</p> <p>5 this issue of the 75 percent of 1.1 centimeters</p> <p>6 indicating proper tensioning?</p> <p>7 A. That's a concept that we all have -- have --</p> <p>8 we, as surgeons, we know we don't want to bring it</p> <p>9 tighter than that. But we learned that with the</p> <p>10 pubourethral slings.</p> <p>11 Q. Okay. So are you saying no, you didn't</p> <p>12 personally discuss that issue or because everyone</p> <p>13 already knew it anyway?</p> <p>14 A. Right. This is -- this is a common surgical</p> <p>15 knowledge, which Ethicon may or may not have known. I</p> <p>16 don't know if they -- if they knew it. This is just a</p> <p>17 personal observation.</p> <p>18 Q. So you believe that Ethicon properly</p> <p>19 instructs physicians on how to tension the TVT; right?</p> <p>20 A. They -- they cover that in the IFU.</p> <p>21 Q. Do you agree that the strongest unmet need</p> <p>22 with the TVT is the ability to adjust tension both</p> <p>23 intraoperatively and post-operatively?</p> <p>24 MR. SNELL: Form.</p>	<p style="text-align: right;">Page 152</p> <p>1 A. That's -- that's part of the art of surgery</p> <p>2 that I described before.</p> <p>3 Q. So you do agree with that; right?</p> <p>4 A. Repeat that.</p> <p>5 Q. So do you agree with, quote, there is no</p> <p>6 calibration to let you know when you have the tension</p> <p>7 right, close quote?</p> <p>8 A. No, we know -- we know when the tension is</p> <p>9 right. We have experience -- enough experience to</p> <p>10 know when the tension is right.</p> <p>11 It's extremely subjective, but I can tell</p> <p>12 you if you, at the end of your surgery, you see that</p> <p>13 width that goes underneath, that width that has been</p> <p>14 shown study after study, that is effective, if you</p> <p>15 know that is not the width you have at the end of your</p> <p>16 surgery, you overtensioned it.</p> <p>17 Q. But there's not like a general calibration</p> <p>18 for that; right? Or is there? I mean, is the general</p> <p>19 calibration the 75 percent of 1.1 centimeters, is that</p> <p>20 the general calibration for everybody or no?</p> <p>21 MR. SNELL: Form.</p> <p>22 A. It's a visual inspection.</p> <p>23 Q. (By Mr. De La Cerda) So is that a yes?</p> <p>24 MR. SNELL: Objection, asked and answered.</p>
<p style="text-align: right;">Page 151</p> <p>1 A. Well, there's no -- no way to assess</p> <p>2 post-operatively. You're going to close and there's</p> <p>3 no -- no study that says how you're going to tension</p> <p>4 it. We try to make an inference with biomechanics.</p> <p>5 Q. (By Mr. De La Cerda) But do you agree</p> <p>6 with that statement? That the strongest unmet need</p> <p>7 of the TVT's ability to adjust tension both</p> <p>8 intraoperatively or post-operatively, do you agree</p> <p>9 or disagree with that statement?</p> <p>10 A. I --</p> <p>11 MR. SNELL: Form.</p> <p>12 Go ahead.</p> <p>13 A. I would agree to an extent, but it's so --</p> <p>14 so vague that I cannot tell you that I agree</p> <p>15 completely with it.</p> <p>16 Q. (By Mr. De La Cerda) Do you agree that</p> <p>17 the mesh and TVT may be too wide?</p> <p>18 MR. SNELL: Form.</p> <p>19 A. I don't -- no, I think it has shown to be of</p> <p>20 the -- of the right -- of the right width to work</p> <p>21 clinically.</p> <p>22 Q. (By Mr. De La Cerda) Do you agree that</p> <p>23 there is no calibration to let you know when you</p> <p>24 have the tension right?</p>	<p style="text-align: right;">Page 153</p> <p>1 A. Yeah, that's a general calibration that is</p> <p>2 been used -- I'm sorry, Burt.</p> <p>3 MR. SNELL: I said, objection, asked and</p> <p>4 answered.</p> <p>5 Go ahead and answer it.</p> <p>6 Q. (By Mr. De La Cerda) Do you agree that</p> <p>7 there is no -- quote, there is no consensus on the</p> <p>8 amount of tension needed and many feel that the</p> <p>9 tension will vary based on patient presentation and</p> <p>10 patient anatomy? Do you agree with that?</p> <p>11 MR. SNELL: Form.</p> <p>12 A. It's -- I would have to agree that it</p> <p>13 changes from patient to patient and that's one of the</p> <p>14 biggest challenges not only in this proceeding, any</p> <p>15 surgery.</p> <p>16 Q. (By Mr. De La Cerda) Are you going to</p> <p>17 offer the opinion that tensioning of the TVT sling</p> <p>18 is the same regardless of whether the sling is made</p> <p>19 of mechanically cut mesh or laser cut mesh?</p> <p>20 A. You're going to visually see at the end of</p> <p>21 your procedure and you know if you tensioned it right</p> <p>22 when you look at it.</p> <p>23 Q. So tensioning might change as long as the</p> <p>24 width that you're looking for is correct?</p>

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<p>1 A. I just say visually see. I don't know how</p> <p>2 another way you're going to see if it's not visually.</p> <p>3 Q. Right.</p> <p>4 A. But it's -- what I -- my opinion is that</p> <p>5 once you -- once you place a sling, that being laser</p> <p>6 cut or mechanically cut, at the end of your procedure,</p> <p>7 that sling needs to look the way -- in a way that it</p> <p>8 covers the mid urethra to an extent of at least .75 to</p> <p>9 1-centimeter.</p> <p>10 Q. Do you agree that a responsible medical</p> <p>11 device company would determine the proper way to place</p> <p>12 a device before putting that product on the market?</p> <p>13 MR. SNELL: Form.</p> <p>14 A. They -- they have no way -- we have no way</p> <p>15 to -- to -- to communicate that to each other. That</p> <p>16 is -- that is the hard part of surgery.</p> <p>17 I think that when they say, "Do not</p> <p>18 overtension it," and when they say, "You need to have</p> <p>19 experience in continence procedures," and when they</p> <p>20 say, "This is not a comprehensive guide for continence</p> <p>21 care," I think that's accurate and fair and as a</p> <p>22 surgeon you understand that.</p> <p>23 Q. (By Mr. De La Cerda) And so this question</p> <p>24 is really more of a general proposition, though.</p>	<p>1 There's a fault question on -- earlier we</p> <p>2 discussed your work as a consultant for Ethicon and we</p> <p>3 briefly discussed what you estimated to be what you</p> <p>4 had received from Ethicon in compensation for that.</p> <p>5 In another case, the Raviola case, which you</p> <p>6 may recall, there was actually a production of the</p> <p>7 payments and it was produced in a -- in hard copy --</p> <p>8 and this question is probably really for Burt.</p> <p>9 MR. DE LA CERDA: If I forward that to you,</p> <p>10 can you send that to us in like an Excel or</p> <p>11 whatever it originally came in because the print</p> <p>12 is tiny?</p> <p>13 MR. SNELL: Okay. Yeah, I mean -- well, I</p> <p>14 can do my best.</p> <p>15 MR. DE LA CERDA: Okay.</p> <p>16 MR. SNELL: I've been trying to send</p> <p>17 e-mails. My e-mail is not working. It's not</p> <p>18 letting me send stuff. I have something</p> <p>19 important to send. It's not related to this</p> <p>20 deposition. I've been trying all morning. Is</p> <p>21 the Internet --</p> <p>22 MR. DE LA CERDA: It's coming off and on for</p> <p>23 me.</p> <p>24 I'm forwarding this to you and then if we</p>
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<p>1 Would you agree that a responsible medical device</p> <p>2 company would determine the proper way to place a</p> <p>3 device before putting that product on the market?</p> <p>4 MR. SNELL: Same objection, asked and</p> <p>5 answered.</p> <p>6 A. That's where -- that's where all the studies</p> <p>7 with cadavers come in.</p> <p>8 Q. (By Mr. De La Cerda) So the answer is</p> <p>9 yes; right?</p> <p>10 A. Yes, the device company does that.</p> <p>11 Q. Okay. Shifting gears to a new issue.</p> <p>12 Before I do that, are you okay? Do you want</p> <p>13 to take a break at all?</p> <p>14 A. No, I'm okay, if you guys are okay.</p> <p>15 MR. SNELL: What time are we going to have</p> <p>16 lunch?</p> <p>17 MR. DE LA CERDA: Yeah, it's almost noon.</p> <p>18 Do you want to do it now.</p> <p>19 MR. SNELL: If he's fine, I'm fine.</p> <p>20 (Thereupon, a recess was taken from</p> <p>21 11:47 a.m. until 12:00 p.m., after which the</p> <p>22 following proceedings were held:)</p> <p>23 Q. (By Mr. De La Cerda) So we're back on the</p> <p>24 record.</p>	<p>1 can get the native version. It looks like it was</p> <p>2 an Excel that was then printed off, but the type</p> <p>3 on it is really small and then that will</p> <p>4 provide -- this is what Ethicon shows its records</p> <p>5 of payments and then that can kind of settle that</p> <p>6 issue.</p> <p>7 THE WITNESS: Yeah, it was actually</p> <p>8 presented on the Cavness trial.</p> <p>9 MR. DE LA CERDA: Oh, okay.</p> <p>10 THE WITNESS: It was in very small -- very</p> <p>11 small letters.</p> <p>12 MR. DE LA CERDA: Okay.</p> <p>13 THE WITNESS: And just as clarifying that</p> <p>14 number, what was allocated to pay me, not actual</p> <p>15 payments.</p> <p>16 MR. DE LA CERDA: Okay. So we'll have to</p> <p>17 clear that up, but if, Burt, you can take a look</p> <p>18 at getting us that version, thanks.</p> <p>19 Q. (By Mr. De La Cerda) Okay. All right.</p> <p>20 The issues that I'm about to discuss will relate to</p> <p>21 TVT, TVT-O, Gynemesh, Prolift and Prosima, so I'm</p> <p>22 going to do it all at once.</p> <p>23 First, you're aware that the TVT and TVT-O</p> <p>24 are made of Prolene mesh, which is constructed of</p>

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<p>1 knitted filaments of extruded polypropylene strands, 2 identical in composition to that used in Prolene 3 polypropylene nonabsorbable surgical suture; correct? 4 A. I agree with that. 5 Q. You're also aware that the mesh in Gynemesh, 6 Prolift, and Prosima is Prolene Soft, which is also 7 constructed of knitted filaments of extruded 8 polypropylene identical in composition to Prolene 9 polypropylene suture; correct? 10 A. To a -- to a -- identical in composition, 11 yes. 12 Q. And the IFUs for the TVT, the TVT-O, 13 Gynemesh, Prolift and Prosima all characterize Prolene 14 as inert; correct? 15 A. They -- they characterize it as that word 16 inert, yeah. 17 Q. They state: "This material, when used as a 18 suture, has reported to be nonreactive and retain its 19 strength indefinitely in clinical use"; right? 20 A. I -- I'm aware of that statement, yes. 21 Q. They also -- the IFUs for those products 22 also state: "The material is not absorbed nor is it 23 subject to degradation or weakening by the action of 24 tissues enzymes"; right?</p>	<p>1 strength of the suture on testing that was done before 2 placing it on a patient. 3 Q. (By Mr. De La Cerda) Okay. So why would 4 it be desirable for a human implant to have those 5 characteristics that it doesn't degrade, that it's 6 inert, that's it's nonreactive? 7 MR. SNELL: Same objection. 8 Go ahead. 9 A. It is -- it translates, theoretically, on 10 the durability of the repair. 11 Q. (By Mr. De La Cerda) Because these mesh 12 implants are intended to be permanent implants; 13 correct? 14 A. They're intended to -- to last a lifetime if 15 you can make it interact in a way that it can last a 16 lifetime. In other words, if the host doesn't change, 17 you'll want that implant to work and give you 18 durability. 19 Q. Now you're aware that as early at 1987, 20 Ethicon had evidence of degradation of Prolene in the 21 human body; correct? 22 A. I -- I don't believe that they call it 23 degradation in the sense that we interpret 24 degradation. There's -- there's degradation from the</p>
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<p>1 A. That's a statement on the IFU. 2 Q. The mesh in these products not being -- or 3 strike that. 4 The mesh in these products being nonreactive 5 or inert or not subject to degradation, that's a 6 property or those are properties that are desirable 7 for an implant designed for a human body; right? 8 MR. SNELL: Form, overbroad. 9 A. That -- that is -- that is a characteristic 10 that we did not see in other types of materials and 11 that we're pursuing when we placed those sutures. 12 Q. (By Mr. De La Cerda) Okay. Why would you 13 want a human -- an implant designed to be implanted 14 in humans to be inert or nonreactive or not subject 15 to degradation? 16 MR. SNELL: Objection, overbroad. 17 Go ahead. 18 A. The degradation has to -- has to do with -- 19 the way we interpret degradation has to do with 20 absorbables or partially absorbable sutures. 21 The way that non- -- nonreactive means that 22 there's no reaction to hydrolysis. 23 And the way that it was described as non- -- 24 nondegraded is it was that there was no loss on the</p>	<p>1 biomechanical point of view and there's degradation 2 from what we see in normal life of degradation. 3 Q. Okay. So what is it that you believe that 4 Ethicon saw in terms of degradation in 1987? 5 A. Well, what they saw -- what they saw is 6 purely a microscopic study. If there will be 7 degradation, there will be a significant impact on the 8 durability of the effect of the sling or in the 9 durability of the repair. 10 Q. In the context of safety, though -- strike 11 that. 12 If Prolene has a tendency to degrade in a 13 human body, would that indicate that it's not inert? 14 MR. SNELL: Form, improper hypothetical. 15 A. If it would degrade, it would dissolve. And 16 if it would dissolve, it would just lose all its 17 effect. So whatever -- whatever conclusion is met of 18 degradation is on hypothetical grounds and not based 19 on the evidence that we have. 20 Q. (By Mr. De La Cerda) What evidence are 21 you referencing? 22 A. The durability of a procedure for 23 incontinence on prolapse. 24 (Brief interruption and off the record discussion.)</p>

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<p>1 Q. I can't remember if you were finished with</p> <p>2 your response. If you could read it back.</p> <p>3 (The requested portion of the record was</p> <p>4 read back by the reporter.)</p> <p>5 A. Let me clarify this. The reason why I</p> <p>6 generalize it on incontinence on prolapse is because</p> <p>7 we're talking about more than one product here.</p> <p>8 Q. (By Mr. De La Cerda) Yes, yes.</p> <p>9 And all these products have, within their</p> <p>10 mesh -- one mesh is called regular Prolene or just</p> <p>11 Prolene and the other one is called Prolene Soft, but</p> <p>12 both meshes are made of essentially woven Prolene</p> <p>13 suture. It's the same material as Prolene; right?</p> <p>14 MR. SNELL: Objection.</p> <p>15 A. No, it's not woven.</p> <p>16 Q. (By Mr. De La Cerda) How is it made then?</p> <p>17 A. It's knitted.</p> <p>18 Q. Knitted, okay.</p> <p>19 But it's all made of knitted polypropylene</p> <p>20 that's identical in composition to Prolene; correct?</p> <p>21 A. It's knitted -- it's knitted extruded</p> <p>22 polypropylene.</p> <p>23 Q. It's identical in composition to Prolene</p> <p>24 suture; right?</p>	<p>1 A. And there is -- first of all, there is</p> <p>2 more -- there are three -- there are three parts to</p> <p>3 that question. The first one is the concept of</p> <p>4 degradation. And if Prolene would degrade, all the</p> <p>5 Burches that we did with polypropylene would</p> <p>6 eventually fail. And all the -- and most of the</p> <p>7 slings that we did with polypropylene would eventually</p> <p>8 fail clinically.</p> <p>9 And we know that the evidence points out</p> <p>10 that that's -- that's not the case. That's the first</p> <p>11 part of degradation.</p> <p>12 Number two is polypropylene, the way it</p> <p>13 defines degradation on a dog or in a rabbit or in a</p> <p>14 Himalayan or a Wistar rat or a Himalayan -- Himalayan</p> <p>15 rabbit, the way it's defined cannot be translated</p> <p>16 to -- to a -- to a person because they're completely</p> <p>17 different hosts and the stresses that are placed on --</p> <p>18 on those implants are completely different.</p> <p>19 The immunologic reaction is different and</p> <p>20 the cellular level is different, cellular findings are</p> <p>21 different. And, finally, is the concept that -- that</p> <p>22 Prolene and -- would -- would degrade and create</p> <p>23 anything beyond what the sling would create. No, they</p> <p>24 stay -- they're both exactly the same, the same. Not</p>
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<p>1 A. It is -- it has been shown to have the same</p> <p>2 level of crystallinity as Prolene suture.</p> <p>3 Q. If there were findings as to Prolene suture,</p> <p>4 would those findings, the characteristics of Prolene</p> <p>5 suture, have relevance to meshes that are also made of</p> <p>6 extruded polypropylene that's identical in composition</p> <p>7 to Prolene suture?</p> <p>8 MR. SNELL: Form, vague.</p> <p>9 A. I did not get that one. Sorry.</p> <p>10 (The requested portion of the record was</p> <p>11 read back by the reporter.)</p> <p>12 A. As it pertains to composition, the evidence</p> <p>13 shows that TVT-O and Prolene sutures, that's the</p> <p>14 extent of the evidence, has -- has the same</p> <p>15 crystallinity. When we define crystallinity, is the</p> <p>16 most accurate way to evaluate that one material is</p> <p>17 like the other.</p> <p>18 Q. (By Mr. De La Cerda) Well, what I'm</p> <p>19 saying, though, is if there is a finding about a</p> <p>20 characteristic of Prolene sutures like, for example,</p> <p>21 degradation, if Prolene sutures degrade in the human</p> <p>22 body, can we also say or is that evidence of that</p> <p>23 Prolene mesh would also degrade in the human body?</p> <p>24 MR. SNELL: Form.</p>	<p>1 exactly, but they're both very similar implants.</p> <p>2 So those are the three -- three aspects to</p> <p>3 your question, and I know it's an extremely elaborate</p> <p>4 answer for probably a much more straightforward</p> <p>5 question. But there's -- the concept of degradation,</p> <p>6 I would have to accept that concept to agree with</p> <p>7 your -- with what you just presented.</p> <p>8 Q. (By Mr. De La Cerda) I think step one is</p> <p>9 we need to define what we're talking about by</p> <p>10 degradation.</p> <p>11 We know that in 1987 there was a study done</p> <p>12 by Ethicon on explanted Prolene suture from humans;</p> <p>13 right?</p> <p>14 A. On explanted and not -- I believe it's from</p> <p>15 the dog study.</p> <p>16 Q. There is one of humans, too. Have you seen</p> <p>17 that one?</p> <p>18 A. No, I haven't -- haven't. I'm not aware of</p> <p>19 that one.</p> <p>20 Q. Okay. If there's a study from 1987 on --</p> <p>21 and these are Prolene sutures explanted from humans,</p> <p>22 if those show the cracking and degrading that's</p> <p>23 indicative of degraded polypropylene, that's the kind</p> <p>24 of degradation that I'm talking about.</p>

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<p>1 A. Are you referring to the eye study?</p> <p>2 Q. I'm sorry?</p> <p>3 A. To the eye study. Are you referring to the</p> <p>4 polypropylene being removed from the eye?</p> <p>5 Q. Vascular -- I believe they were implanted in</p> <p>6 the heart. Unfortunately, I didn't bring that study</p> <p>7 with me. I assumed you would already be aware of it.</p> <p>8 My understanding is they were explanted from</p> <p>9 the hearts of the patients. They were Prolene sutures</p> <p>10 explanted from the heart of human patients.</p> <p>11 Are you aware of that one?</p> <p>12 A. No, I'm not aware. I know there is a study</p> <p>13 on blood vessels and I know that there is a study</p> <p>14 of -- on the eye and I know about the dog study.</p> <p>15 Q. Okay.</p> <p>16 MR. SNELL: For clarification purposes, you</p> <p>17 have -- maybe if you knew -- I can tell you -- I</p> <p>18 know what the name of it is. I mean, if that</p> <p>19 would ring a bell with him.</p> <p>20 MR. DE LA CERDA: Professor --</p> <p>21 MR. SNELL: Gudion, blood vessels.</p> <p>22 THE COURT REPORTER: Can you spell that one?</p> <p>23 MR. DE LA CERDA: I think it's G-u-d-o-i-n</p> <p>24 or something like that. That's the professor's</p>	<p>1 on and when they look at that cracking, it's</p> <p>2 believed to be polypropylene that's cracking and</p> <p>3 degrading.</p> <p>4 Now you've seen studies that have discussed</p> <p>5 that issue; right?</p> <p>6 A. I'm -- I'm aware of the paper by Clavé.</p> <p>7 Q. Okay.</p> <p>8 A. By one of the Clavés, by the way, not --</p> <p>9 Q. Is there a brother, like an evil twin?</p> <p>10 A. So I am aware of that paper and in that same</p> <p>11 paper they cite the UV -- ultraviolet degradation, but</p> <p>12 I am also aware that that paper was about normal</p> <p>13 samples.</p> <p>14 I'm also aware that the number of</p> <p>15 low-density polypropylene study was less than -- I</p> <p>16 believe it was a quarter of the sample and -- I don't</p> <p>17 have to believe it, I actually have it here.</p> <p>18 Q. You're welcome to pull out anything you'd</p> <p>19 like to review.</p> <p>20 What I'm trying to get at -- I'm just trying</p> <p>21 to get us to agree at least on a definition of</p> <p>22 degradation that I'm going to ask you about. And what</p> <p>23 I'm trying to say is that's the version of degradation</p> <p>24 I'd like to ask you about.</p>
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<p>1 last name.</p> <p>2 Q. (By Mr. De La Cerda) Does that ring a</p> <p>3 bell?</p> <p>4 A. It's -- I am -- I read that. I do recall</p> <p>5 reading it and I do recall that it was a very thin</p> <p>6 polypropylene suture that was hand tied, but</p> <p>7 there's -- I don't know how that translate to</p> <p>8 degradation.</p> <p>9 Q. (By Mr. De La Cerda) Okay. So the</p> <p>10 finding in that study was at the surface, that there</p> <p>11 was cracking on the surface of the suture; right?</p> <p>12 And that when they tested the material from the</p> <p>13 cracking, that it was indicative of oxidative</p> <p>14 degradation to polypropylene; right?</p> <p>15 MR. SNELL: I'm going to object on</p> <p>16 foundation.</p> <p>17 Go ahead.</p> <p>18 A. I cannot confirm that, no.</p> <p>19 Q. (By Mr. De La Cerda) Okay. Well, what</p> <p>20 I'm trying to do is define the degradation I'm</p> <p>21 talking about. And I think this is even in the</p> <p>22 studies that discuss it, degradation, and there have</p> <p>23 been in the studies discussion of the surface of</p> <p>24 polypropylene has some sort of cracking that's going</p>	<p>1 Now, I know you're already going to tell me</p> <p>2 that's not clinically significant. I know you're</p> <p>3 going to tell me it's not going to matter. I know</p> <p>4 that. What I'm trying to first get is let's get an</p> <p>5 agreement on that's the degradation I'm talking about</p> <p>6 and then we can go through the -- to kind of finish up</p> <p>7 the questions because you'll end up telling me that it</p> <p>8 doesn't need to be in the IFU.</p> <p>9 So focusing, first, on the degradation, the</p> <p>10 version that I'm talking about is the cracking, the</p> <p>11 surface cracking that happens of the polypropylene</p> <p>12 that's at least been seen and reported on in some of</p> <p>13 the studies. Is that version of degradation, is that</p> <p>14 clinically significant or clinically relevant such</p> <p>15 that it needs to be in the IFU for the TVT, TVT-O,</p> <p>16 Gynemesh, Prolift and Prosima?</p> <p>17 MR. SNELL: Objection, lacks foundation.</p> <p>18 Go ahead.</p> <p>19 A. The way it stands right now, with the</p> <p>20 studies that I have seen, specifically the ones on --</p> <p>21 in general polypropylene -- the ones on the eye, I</p> <p>22 believe I saw that. The way it stands right now, that</p> <p>23 type of degradation has not been shown on the -- on</p> <p>24 actual samples of slings. It has been shown in</p>

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<p>1 abnormal samples, not in slings that work or come --</p> <p>2 or have the clinical results that we have seen on</p> <p>3 reports and it have -- it have not been shown in</p> <p>4 any -- any studies having a clinical impact.</p> <p>5 Q. (By Mr. De La Cerda) Okay. What do you</p> <p>6 mean by "abnormal slings"?</p> <p>7 A. If there is a sling that has an exposure,</p> <p>8 and especially slings that are exposed to a surface,</p> <p>9 then that will be abnormal sample.</p> <p>10 Q. Okay. Exposed to what kind of surface?</p> <p>11 A. To the vagina or the bladder or the bowel.</p> <p>12 Q. Okay. So is there something that's</p> <p>13 happening during that exposure that -- that your</p> <p>14 belief is causing this phenomenon of degradation?</p> <p>15 MR. SNELL: Objection. Hold on.</p> <p>16 Misstates -- I don't think he testified, Counsel,</p> <p>17 that he believes in degradation. I think you're</p> <p>18 taking what he said -- I think you're misstating</p> <p>19 his answer.</p> <p>20 Go ahead.</p> <p>21 A. The -- what we see in abnormal slings is</p> <p>22 that a biofilm is created and this biofilm is -- has</p> <p>23 been seen in catheters, it has been seen in IUDs, it</p> <p>24 has been seen in other implants that are exposed to</p>	<p>1 storage. This is completely different from -- from</p> <p>2 what is used in slings in prolapse. So there's --</p> <p>3 it's a hypothesis. That's probably upgrading it to a</p> <p>4 hypothesis.</p> <p>5 Q. Ultimately you believe, though, that the</p> <p>6 cracking that's seen when the studies are discussing</p> <p>7 degradation is really a biofilm and not the</p> <p>8 polypropylene itself; right?</p> <p>9 A. I -- I don't know if it's the biofilm or</p> <p>10 it's a matter of technique or if it's a stressor that</p> <p>11 was placed on the sample on retrieval. We -- we don't</p> <p>12 know that. And most -- most importantly, we know that</p> <p>13 probably any -- regardless of the reason why it</p> <p>14 happens, it doesn't translate in any physical outcome,</p> <p>15 in a clinical significant outcome.</p> <p>16 Q. What about the erosions, though? So you</p> <p>17 mentioned that they were abnormal meshes that had</p> <p>18 eroded and were exposed to air, isn't the fact there</p> <p>19 is an erosion, isn't that some sort of clinical --</p> <p>20 clinically significant event?</p> <p>21 MR. SNELL: Form.</p> <p>22 A. No, the exposed segment of the sling doesn't</p> <p>23 mean that it eroded. The most frequently -- the</p> <p>24 most -- normally, the most frequent reason why you see</p>
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<p>1 air.</p> <p>2 Q. (By Mr. De La Cerda) Okay. So is that --</p> <p>3 is that your explanation of what you believe is</p> <p>4 actually being seen when we see this cracking?</p> <p>5 A. That -- that is -- that is actually what --</p> <p>6 what I see, the only correlation that I can put</p> <p>7 together with the cracking.</p> <p>8 There's no other explanation based on what I</p> <p>9 know and what I have researched that mechanical stress</p> <p>10 retrieval or a biofilm.</p> <p>11 Q. Okay. We know -- well, you know that raw</p> <p>12 polypropylene without any antioxidants would degrade</p> <p>13 in the human body. Do you know that or no? Or do you</p> <p>14 believe that or no?</p> <p>15 A. No, there's no evidence that there's</p> <p>16 degradation.</p> <p>17 Q. Okay. Do strong oxidizers like peroxide, do</p> <p>18 those affect raw polypropylene or no?</p> <p>19 A. The only report that I was able to find on</p> <p>20 it was in containers, which is different from this --</p> <p>21 it's the same hydrocarbon, but different containers on</p> <p>22 a surface outside.</p> <p>23 Q. Okay.</p> <p>24 A. Actual containers that were used for</p>	<p>1 an exposed sling or a mesh is because there's a bone</p> <p>2 healing that -- the dehiscence of the wound, there is</p> <p>3 a dehiscence of the wound, there is a disorder of the</p> <p>4 wound healing.</p> <p>5 So we have seen disorders of wound healing</p> <p>6 in patients that have prolapse even before we place --</p> <p>7 we replace it, and we actually have seen it with</p> <p>8 sutures. Not only with polypropylene sutures, we have</p> <p>9 seen it with polyester sutures, specifically, and we</p> <p>10 have seen it with GORE-TEX sutures.</p> <p>11 And there's actual clinical evidence that</p> <p>12 shows these abnormal wound healing occurring on the</p> <p>13 presence of these sutures, and also with native</p> <p>14 tissue. So this is not that the sling work itself</p> <p>15 around and erode. This is an incision that has been</p> <p>16 open.</p> <p>17 Q. (By Mr. De La Cerda) And is there any --</p> <p>18 and what's responsible for the poor wound healing or</p> <p>19 the wound healing issue?</p> <p>20 A. There are a variety of factors. These are</p> <p>21 defects in the fibromuscular layer, specifically, as I</p> <p>22 place -- as I wrote in my report, loss of tensile</p> <p>23 strength in the abdominal sutures that put the wound</p> <p>24 together.</p>

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<p>1 Number two, there are mechanical factors.</p> <p>2 Number three, there are actual wound-healing</p> <p>3 factors, such as immune disorders, poor tissue</p> <p>4 healing, cigarette smoking, and finally hematomas,</p> <p>5 just to mention a few.</p> <p>6 And these conditions may predispose a wound</p> <p>7 to open and expose the graft. It may predispose the</p> <p>8 wound not to heal properly over a suture and it may</p> <p>9 predispose the wound not to heal properly just over</p> <p>10 native tissue.</p> <p>11 Q. Have you -- are you aware of an exposure and</p> <p>12 erosion ever happening not related to a wound healing</p> <p>13 issue?</p> <p>14 A. No, that's -- that's -- is a problem of</p> <p>15 wound healing.</p> <p>16 Q. And that's it?</p> <p>17 A. And that's what I see consistently.</p> <p>18 Q. But it's your belief that that's the only</p> <p>19 reason why there might be an exposure or erosion is</p> <p>20 because of wound healing; right?</p> <p>21 A. It is the most viable factor of the three</p> <p>22 fact- -- of the three -- of the interaction between a</p> <p>23 graft on a host, is the most viable factor is the</p> <p>24 host. And the -- the sling's consistent. Or the --</p>	<p>1 that those with the most experience have the lowest</p> <p>2 rate of -- lowest rate of problems. Not only this</p> <p>3 surgery, any other surgery, but the most consistent</p> <p>4 part is the prosthesis, the polypropylene.</p> <p>5 Q. Do you believe that mesh degrading or</p> <p>6 breaking down can lead to an erosion or exposure or</p> <p>7 no?</p> <p>8 MR. SNELL: Foundation.</p> <p>9 A. There's -- there's no evidence that that's</p> <p>10 the case.</p> <p>11 Q. (By Mr. De La Cerda) Do you believe that</p> <p>12 polypropylene can become brittle?</p> <p>13 A. How -- how do we define brittle?</p> <p>14 Q. That's a good question.</p> <p>15 A. You're going to probably --</p> <p>16 Q. What's your understanding of the term</p> <p>17 "brittle"?</p> <p>18 A. Brittle is weak. Brittle could be friable.</p> <p>19 Decreased tensile strength to put it in exact terms.</p> <p>20 Q. So using that explanation of what brittle</p> <p>21 means to you, do you believe that polypropylene can</p> <p>22 become brittle?</p> <p>23 A. No.</p> <p>24 Q. Okay. So now let's get to the question</p>
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<p>1 or the polypropylene is a consistent material. And</p> <p>2 there's obviously the third one, which is the</p> <p>3 insertion, the technique, but if you really look at</p> <p>4 technique being constant, it's always a wound healing</p> <p>5 issue.</p> <p>6 Q. So one of the problems could be the doctor's</p> <p>7 fault, the other problem could be the patient's fault</p> <p>8 because of their body and their wound healing, but</p> <p>9 third issue can't be the implant because it is what it</p> <p>10 is and it's --</p> <p>11 A. I would not simplify just with it being a</p> <p>12 fault. We -- this is not -- these are not issues that</p> <p>13 are just -- that just happened with -- with mesh.</p> <p>14 We -- we know that these issues go way -- for any</p> <p>15 prosthetic material, way back before any prosthetic</p> <p>16 material. We know that these issues happen with</p> <p>17 polyester sutures in uterosacral ligament suspensions.</p> <p>18 We know that there are instances in which there has</p> <p>19 been no mesh, there being a suture and the suture had</p> <p>20 to be removed. And we know there are instances in</p> <p>21 which we don't use a mesh at all and that incision</p> <p>22 opens up. The most viable aspect is the host.</p> <p>23 There's definitely a variation on the insertion</p> <p>24 technique and I think that by now we all have evidence</p>	<p>1 about your opinion. Should Prolene's tendency to</p> <p>2 degrade in the human body be included in the IFUs for</p> <p>3 the TVT, TVT-O, Gynemesh, Prolift and Proxima?</p> <p>4 MR. SNELL: Lacks foundation, misstates,</p> <p>5 opinion testimony.</p> <p>6 A. There's -- there's nothing to place the</p> <p>7 result of degradation.</p> <p>8 Q. (By Mr. De La Cerda) And your basis for</p> <p>9 that opinion is what?</p> <p>10 MR. SNELL: Asked and answered.</p> <p>11 A. That degradation has not been defined in a</p> <p>12 reproducible scientific way to have -- to be present</p> <p>13 or, if present, to have any consequences in clinical</p> <p>14 outcomes.</p> <p>15 MR. DE LA CERDA: All right. I think that's</p> <p>16 a good break point. It's 12:30.</p> <p>17 (Thereupon, a lunch recess was taken from</p> <p>18 12:30 p.m. until 1:20 p.m., after which the</p> <p>19 following proceedings were held:).</p> <p>20 Q. (By Mr. De La Cerda) All right. Doctor,</p> <p>21 we're back on the record. There is one question I</p> <p>22 wanted to ask you on the degradation issue.</p> <p>23 If Prolene's tendency to degrade the human</p> <p>24 body is clinically significant, clinically relevant</p>

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<p>1 and statistically significant, should that information</p> <p>2 be included in the IFUs for the TVT, TVT-O, Gynemesh,</p> <p>3 Prolift and Prosima?</p> <p>4 MR. SNELL: Objection, foundation, form.</p> <p>5 Go ahead.</p> <p>6 A. Any -- any significant clinical response</p> <p>7 that deviates from what's reported in randomized</p> <p>8 control trials should be -- should be a matter of</p> <p>9 addressing it, regardless if there is a degradation</p> <p>10 there underneath or not. And there -- there are</p> <p>11 systems in place that allows for that reporting, more</p> <p>12 than one system, actually.</p> <p>13 Q. (By Mr. De La Cerda) So any risk or</p> <p>14 complication that's clinically significant,</p> <p>15 clinically relevant and statistically significant,</p> <p>16 any risk or complication that's like that should be</p> <p>17 included in the IFU, do you agree with that?</p> <p>18 MR. SNELL: Form, foundation, misstates.</p> <p>19 A. If there's -- anything that is clinically</p> <p>20 significant, statistically significant, let's say we</p> <p>21 have a voiding dysfunction that is higher than would</p> <p>22 happen with a Burch procedure, if we have pain, any</p> <p>23 type of an incidence of urge incontinence or urge</p> <p>24 incontinence, incidents of any -- that should be</p>	<p>1 elution method showed cell lysis and toxicity;</p> <p>2 correct?</p> <p>3 A. There was one other place, and I was able to</p> <p>4 see that on company documents. There was one other</p> <p>5 place in which they saw that there was a little</p> <p>6 cytotoxicity, but when it was -- it could never be</p> <p>7 reproduced, actually, when it was redone in the</p> <p>8 agarose, in the agarose form, there was -- in the</p> <p>9 agarose overlay method, it was not -- it was not</p> <p>10 cytotoxicity.</p> <p>11 And this is significant because the -- when</p> <p>12 you do a drug elution test, essentially, you're</p> <p>13 immersing the cells on a pool of this -- of this</p> <p>14 polypropylene. It will be -- it's a huge amount.</p> <p>15 It's an amount that you, on purpose, make it -- make</p> <p>16 it toxic. The toxicity -- the toxicity is -- is</p> <p>17 supposed to affect a lot more than this.</p> <p>18 One of the biggest drawbacks of cytotoxicity</p> <p>19 assays is that you cannot have a positive control. So</p> <p>20 when you put agarose on it, you neutralize and you</p> <p>21 make it more real. You neutralize it and make it more</p> <p>22 real.</p> <p>23 Q. In one of those two testing methods</p> <p>24 cytotoxicity was shown; right?</p>
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<p>1 addressed. If it's different from the RCTs. But if</p> <p>2 you're going to challenge what's reported on RCTs,</p> <p>3 then you need to come up with a similar number of</p> <p>4 patients and you need to have some statistical</p> <p>5 validity to it.</p> <p>6 Q. (By Mr. De La Cerda) Okay. Moving on to</p> <p>7 a new issue and this one involves TVT and TVT-O.</p> <p>8 What does cytotoxicity mean?</p> <p>9 A. It means in the -- in experiment, the number</p> <p>10 of cells that are not viable after exposure to an</p> <p>11 agent is lower than the expected of the benchmark we</p> <p>12 established.</p> <p>13 Q. The definition you gave me, which, by the</p> <p>14 way, is very accurate in a certain sense. It's funny,</p> <p>15 so you told me exactly what the scientific definition</p> <p>16 is. The other thing I was asking -- that I was</p> <p>17 thinking in my mind is cytotoxicity, what does that</p> <p>18 word mean, literally?</p> <p>19 MR. SNELL: Form.</p> <p>20 A. It means it will -- it means toxicity to the</p> <p>21 cell.</p> <p>22 Q. (By Mr. De La Cerda) Right. And you're</p> <p>23 aware that the cytotoxicity assessment of the</p> <p>24 Ulmsten Prolene polypropylene sling, using the ISO</p>	<p>1 A. It was in one plate. It was not</p> <p>2 scientifically significant to it. When normal</p> <p>3 polypropylene was -- was examined on L929 mouse</p> <p>4 fibroblast cells, there was no cytotoxicity.</p> <p>5 Q. Have you studied what happens to tissues</p> <p>6 when it's exposed to a cytotoxic substance?</p> <p>7 A. Yes, I have.</p> <p>8 Q. And can you explain what those studies were?</p> <p>9 A. Before going to OB/GYN, I did a fellowship</p> <p>10 on molecular pharmacology, and I did a flow cytometry</p> <p>11 and cytotoxicity assays, that's what I did every day.</p> <p>12 Q. Okay.</p> <p>13 A. And we use different agents. So there's --</p> <p>14 one thing that we know that tissue configures a</p> <p>15 protection different from cells. Tissue makes --</p> <p>16 makes the viability of cells coming -- mediating by</p> <p>17 whatever response that you may have to a cytotoxic</p> <p>18 agent.</p> <p>19 So far, and there has not been any evidence</p> <p>20 that polypropylene is a cytotoxic in the muscle that</p> <p>21 been by biopsy or by any other -- other test.</p> <p>22 Q. Would you agree that necrotized tissue</p> <p>23 surrounding mesh could lead to erosion or exposure of</p> <p>24 the mesh?</p>

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<p>1 A. If you see a necrotic tissue in an incision, 2 it's a wound dehiscence. 3 Q. So do you agree or disagree with that 4 statement -- or that question? 5 MR. SNELL: Form. 6 A. That -- you will have to repeat it. I'm 7 sorry. 8 Q. (By Mr. De La Cerda) Would you agree that 9 necrotized tissue surrounding the mesh could lead to 10 an erosion or exposure of the mesh? 11 A. If it's at the wound, yes, it can lead to 12 that. 13 Q. Should the cytotoxicity assessment of the 14 Ulmsten polypropylene sling showing cytotoxicity be 15 included in the TVT or TVT-O IFUs? 16 MR. SNELL: Form, misstates. 17 A. Once you have a pyrogenicity assays and once 18 you have a drug elution and agarose test, if your 19 testing is negative, you just submit it to the FDA. 20 It doesn't have to be included as cytotoxic because it 21 will be -- it will be inaccurate. 22 Q. (By Mr. De La Cerda) So the answer is no; 23 right? 24 A. No.</p>	<p>1 in terms of grams per square millimeters. 2 Q. And so do you have an understanding of what 3 the significance in terms of risks and 4 complications -- 5 A. I -- I misspoke. 6 Q. Okay. 7 A. I misspoke. It's not per square millimeter. 8 It is per square meter. 9 Q. Okay. 10 A. I can double-check that. 11 Q. Do you have any understanding of what the 12 significance is in terms of risks and complications 13 when you look at lightweight mesh versus heavyweight 14 mesh? 15 MR. SNELL: Form. 16 Go ahead. 17 A. The heavy -- heavyweight meshes with -- not 18 only just with the weight, but with all the other -- 19 the other factors, including fiber size, pore -- pore 20 diameter, and method of coming together, either being 21 knitted or woven, had to do with the tolerability and 22 biocompatibility of the implant. 23 Q. (By Mr. De La Cerda) So let's get back to 24 my question, though. Is there a difference in terms</p>
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<p>1 Q. And what would be your basis for that 2 opinion? 3 A. My -- the review of the -- the review of the 4 cytotoxicity assays that were made available to me 5 through company documents. 6 Q. Okay. And which ones were those? 7 A. The ones on TVT. 8 Q. And those included the ISO agarose diffusion 9 method? 10 A. That includes -- there are two types of 11 tests that were done. There was the agarose, the drug 12 elution, and pyrogenicity and to check for the 13 inflammatory reaction also of injected polypropylene. 14 Q. Any other bases for this opinion? 15 A. This is -- this is the basis for the 16 opinions. 17 Q. Do you know what the significance is of mesh 18 being heavyweight as opposed to lightweight? 19 A. There's -- there's -- the difference -- 20 difference in weight -- in the weight, essentially. 21 Q. And it's really a description of density, 22 right, not actual mass? 23 A. It has -- it has to do with how much per a 24 square -- square millimeter is, how much does it weigh</p>	<p>1 of risks and complications for a patient between 2 lightweight and heavyweight mesh? 3 MR. SNELL: Form. 4 A. Not to the point that has been clinically 5 demonstrated. 6 In theory, we could -- in theory, there is a 7 difference. In the lab, when we use large portions we 8 can infer that, but that has not been shown in the 9 clinical arena of incontinence. 10 Q. (By Mr. De La Cerda) Okay. So now -- 11 okay. 12 First of all, let's discuss, what is the 13 theory of the difference -- the theory of the 14 significance as to risks and complications when you 15 compare lightweight versus heavyweight mesh? 16 A. It's the biomechanical behavior is 17 different. The biomechanical behavior is different 18 not only for that type of preparation, but it's also 19 different for the caliber of the sutures. 20 In other words, if I use a thinner suture, 21 that being polypropylene or any other material, it 22 will -- it can behave differently. It has a tendency 23 to behave differently than a lightweight mesh or a 24 heavyweight mesh.</p>

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<p>1 Q. Okay. In what ways?</p> <p>2 A. In the testing, when you stretch it, when</p> <p>3 you fold it, when you place it and have fibroblast</p> <p>4 growing along the lines of stress of the implant.</p> <p>5 Q. Okay. What about in terms of foreign body</p> <p>6 reaction, is there a difference between lightweight</p> <p>7 and heavyweight mesh?</p> <p>8 A. We used to believe that there was much more</p> <p>9 on the heavyweight meshes, much more foreign body</p> <p>10 reaction. But has been found is that that initial</p> <p>11 reaction of the acute inflammatory -- of the acute</p> <p>12 inflammatory process and eventually of the chronic</p> <p>13 inflammatory process leads to the creation of</p> <p>14 fibroblast.</p> <p>15 What biomechanically has been concluded is</p> <p>16 that that level of stress, the level of stress in</p> <p>17 these implants, the level of tension or forces that</p> <p>18 are applied to these implants, behave differently and</p> <p>19 that seems to determine how fibroblasts grow.</p> <p>20 So the heavyweight and the lightweight</p> <p>21 behave differently. There has not been a single study</p> <p>22 that shows, at a microscopic level, 80,000, 100,000</p> <p>23 samples, but we do have clinical studies that show</p> <p>24 that number of women. So in terms of the clinical</p>	<p>1 MR. SNELL: Form, foundation.</p> <p>2 Go ahead.</p> <p>3 A. I think that their conclusions are very,</p> <p>4 very hypothetical at best.</p> <p>5 Q. (By Mr. De La Cerda) Okay. Would you use</p> <p>6 standard Prolene in the correction of pelvic organ</p> <p>7 prolapse?</p> <p>8 A. We did. Actually, we didn't just use</p> <p>9 Prolene, we use Mersilene. We used Marlex. We used a</p> <p>10 variety of materials before this, before we actually</p> <p>11 use it for slings.</p> <p>12 We didn't use it for slings because by the</p> <p>13 time that midurethral slings came in, we have that</p> <p>14 200-micron -- actually 196-micron fiber with a pore</p> <p>15 size of 1500, and it was -- it was something -- it was</p> <p>16 something that we knew that would match the thinnest</p> <p>17 sutures that we could use for a Burch.</p> <p>18 Q. To be sure I've got an answer to that</p> <p>19 particular question, though, the answer is yes, you</p> <p>20 would use standard Prolene mesh in the surgical</p> <p>21 correction of pelvic organ prolapse; is that right?</p> <p>22 A. Yes.</p> <p>23 Q. Okay.</p> <p>24 A. I could consider using it. There are other</p>
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<p>1 behavior, it's probably less difference than what we</p> <p>2 could see microscopically. In terms of the acute</p> <p>3 inflammatory reaction, the difference between</p> <p>4 200-micron of fiber and a 300-micron fiber is probably</p> <p>5 not that much.</p> <p>6 Q. So do you disagree with the theory that</p> <p>7 lightweight mesh is safer for patients than</p> <p>8 heavyweight mesh for use in the pelvic floor?</p> <p>9 MR. SNELL: Form.</p> <p>10 Go ahead.</p> <p>11 A. I think that's a very broad statement to say</p> <p>12 lightweight meshes for sure are safer. That is a very</p> <p>13 elementary statement that -- for much more complicated</p> <p>14 issue.</p> <p>15 Q. (By Mr. De La Cerda) Okay. Are you</p> <p>16 familiar with Closterhofen, Clinga? Are you</p> <p>17 familiar with Todd Heniford? Are you familiar with</p> <p>18 these physicians' and scientists' opinions about the</p> <p>19 safety of lightweight mesh versus heavyweight mesh?</p> <p>20 A. I am familiar with their work.</p> <p>21 Q. Okay. Do you disagree with their</p> <p>22 conclusions about lightweight mesh being safer for a</p> <p>23 patient as compared to heavyweight mesh?</p> <p>24 A. I think that their --</p>	<p>1 factors that may not lead me to use it, but the weight</p> <p>2 of the mesh is not the only factor.</p> <p>3 Q. So you would disagree with anyone that would</p> <p>4 say that using Prolene mesh in the treatment of pelvic</p> <p>5 organ prolapse is too dangerous and risky. You</p> <p>6 disagree with that; right?</p> <p>7 A. I would disagree with that, yes.</p> <p>8 Q. Have you ever read the deposition of Jorge</p> <p>9 Holste?</p> <p>10 A. I may have read it and if I did, I probably</p> <p>11 read it over a year ago.</p> <p>12 Q. Head of the preclinical department of</p> <p>13 Ethicon for 30 years, german guy, he opined that</p> <p>14 Prolene mesh is heavyweight mesh.</p> <p>15 Does that ring any bells?</p> <p>16 MR. SNELL: Foundation on that one.</p> <p>17 A. Prolene mesh, the way they classify is</p> <p>18 heavy -- heavyweight mesh. There were a number of</p> <p>19 materials that I'm aware that they work with and they</p> <p>20 classify according to weight. From the engineering</p> <p>21 point of view, that might be accurate. From a</p> <p>22 surgical point of view, there are a lot of other</p> <p>23 factors that have to be considered.</p> <p>24 Q. (By Mr. De La Cerda) Okay. Do you agree</p>

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<p>1 or disagree that heavyweight mesh causes greater 2 foreign body reaction than lightweight mesh? 3 MR. SNELL: Form. 4 A. There might have -- there could be in 5 existence something that says that increases the 6 number of neutrophils, but I have not found any -- any 7 utility on clinical care on predicting the behavior of 8 TVT. 9 Q. (By Mr. De La Cerda) So do you agree or 10 disagree with that statement? 11 A. I -- I could not agree or disagree with 12 that. That's so general and I would be speculating on 13 it. 14 Q. Okay. Do you agree or disagree that leaving 15 less mesh material in the patient's body is important 16 because it will reduce the amount of inflammation and 17 foreign body reaction? 18 A. That's -- 19 MR. SNELL: Hold on. You have to give me a 20 chance to object. 21 Overbroad and incomplete hypothetical. 22 A. That's more than a scientific approach. 23 That's a very attractive approach. And that's -- as 24 surgeons, we don't always base what we do on -- on</p>	<p>1 simplistic way of looking at it because a scar does 2 not have the same viscoelastic capabilities of tissue. 3 So you have to -- when you say a scar, it's not 4 necessarily a scar in the way that we see scars. It's 5 viscoelastically it's different. 6 That's why someone can urinate after they 7 have a sling placed and they don't have retention. 8 That's how someone can have normal flows, someone can 9 be continent, at the same time also can go and 10 urinate. 11 Q. Are you familiar with the term "fibrotic 12 bridging"? 13 A. I've heard the term "fibrotic bridging," 14 yes. 15 Q. What's your understanding of that term? 16 A. It's the growth of a fibroblast from one 17 segment to the next. 18 Q. Do you agree or disagree that heavyweight 19 meshes induce more fibrotic bridging tissue reaction 20 causing more shrinkage during maturing of the 21 collagenous tissue? 22 MR. SNELL: Form, foundation. 23 A. I saw it described at one time. I didn't 24 see anything that could conclude it. I did not see a</p>
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<p>1 science, but also on common sense backed by science. 2 And, yeah, if I can take care of something 3 with less mesh, I probably would be attracted to it. 4 On the other side, you need to respect as surgeons 5 that say, "Well, you know, I will use the full-length 6 sling because it has the longest evidence behind it." 7 So in that regard, you're using more material, but you 8 have more evidence behind it. 9 Q. (By Mr. De La Cerda) Do you agree or 10 disagree that reducing the inflammatory reaction of 11 the body will also reduce the risk of contraction or 12 shrinkage of the mesh? 13 MR. SNELL: Same objection. 14 A. We don't -- we don't know that and I could 15 not agree with something that, in general, as a 16 specialty, we don't -- we don't know. 17 The reduced inflammatory reaction may not 18 work for the best. There's a chain of events that 19 happens during the inflammatory process and that leads 20 ultimately to the creation of a fibroblast angle that 21 is what gives the support beyond the implant. 22 Q. (By Mr. De La Cerda) It's scarring; 23 right? 24 A. It is -- it is not a scar. Scar is the most</p>	<p>1 paper that could conclude it. I'm welcome to look at 2 anything that says that fibrotic bridging is 3 significantly more. The first thing I would like to 4 know is how you're going to measure it. 5 Q. (By Mr. De La Cerda) Okay. So I guess 6 you don't have enough information to either agree or 7 disagree; is that right? 8 MR. SNELL: Object, misstates. 9 A. I have -- I have enough information to -- to 10 not agree or disagree with it. And that -- the 11 information that I have is that from one segment to 12 the other, just looking at two segments and the 13 fibroblast that grow between, at one point in time 14 that's not enough to make that conclusion, that 15 fibrotic bridging would cause contraction or 16 anything -- or anything similar like that. 17 There's -- in one of the papers that I gave, 18 there are two papers that I submitted today about the 19 effect of stress on fibroblast growth, and I think 20 that's more complete than fibrotic bridging. 21 Q. (By Mr. De La Cerda) So is it fair to say 22 that you disagree with that statement then? 23 A. I -- I cannot say one way or the other 24 fibrotic bridging. If I would have to commit to</p>

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<p>1 agreeing or disagreeing with it, I think that fibrotic</p> <p>2 bridging is, again, very hypothetical -- hypothetical</p> <p>3 statement. I also believe that I can change my</p> <p>4 opinion based on what I read.</p> <p>5 Q. Okay. So as you sit here today, though, I</p> <p>6 think -- I think what you're saying, as you sit here</p> <p>7 today, is you would have to disagree because you</p> <p>8 believe there's not enough evidence to support the</p> <p>9 statement? I mean, is that what you're saying?</p> <p>10 A. There's not enough evidence to support</p> <p>11 fibrotic bridging. It's a concept that is</p> <p>12 interesting. It's a concept that can be studied.</p> <p>13 It's a concept that has to be taken into the context</p> <p>14 of what -- how fibroblast grow under stress.</p> <p>15 Q. Are you aware that Ethicon's own scientists</p> <p>16 and consultants have opined that Prolene mesh, the</p> <p>17 same mesh in the TVT and TVT-O, is heavyweight as</p> <p>18 opposed to being lightweight?</p> <p>19 MR. SNELL: Lacks foundation.</p> <p>20 A. I -- I -- I haven't seen the opinion of each</p> <p>21 one of them.</p> <p>22 Q. (By Mr. De La Cerda) Okay. So you're not</p> <p>23 aware?</p> <p>24 A. I'm not aware.</p>	<p>1 What would be your basis for not having to</p> <p>2 include it in the IFU?</p> <p>3 A. Number one, it's not evidence -- the concept</p> <p>4 of whatever implications they may have clinically is</p> <p>5 not evidence-based and, number two, there are no</p> <p>6 clinical implications that you can attribute to it.</p> <p>7 Q. Okay. Part of your report discusses the</p> <p>8 MSDS. So you've reviewed the MSDS for the raw</p> <p>9 polypropylene that goes into making the Prolene and</p> <p>10 the TVT, TVT-O, Gynemesh, Prolift and Prosima?</p> <p>11 A. I saw the MSDS about raw -- raw material.</p> <p>12 Q. Right. You're familiar with what a Material</p> <p>13 Safety Data Sheet is?</p> <p>14 A. I learned about Material Safety Data Sheet</p> <p>15 along the lines of this -- of this litigation.</p> <p>16 Q. Okay. So you know that the Material Safety</p> <p>17 Data Sheet states that raw polypropylene is</p> <p>18 incompatible with strong oxidizers, such as peroxides;</p> <p>19 correct?</p> <p>20 A. I read that in the MSDS.</p> <p>21 Q. And as a physician, you know that peroxides</p> <p>22 are present in the human body; right?</p> <p>23 MR. SNELL: Form.</p> <p>24 A. I am not aware of anyone measuring the</p>
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<p>1 Q. Should a discussion of whether Prolene mesh</p> <p>2 is heavyweight be included in the IFUs for the TVT and</p> <p>3 the TVT-O?</p> <p>4 MR. SNELL: Form, foundation.</p> <p>5 A. No, I don't think that -- I actually believe</p> <p>6 that most doctors, if you tell them heavyweight --</p> <p>7 about heavyweight and lightweight meshes, they have</p> <p>8 had to be educated on it.</p> <p>9 I know that the great majority of them are</p> <p>10 probably going to look at me and say, "Okay, Jaime, so</p> <p>11 you're telling me about heavyweight and lightweight</p> <p>12 and all these different aspects, tell me how does this</p> <p>13 translate in the care of my patients?" And I would</p> <p>14 disagree with -- with any statement that makes</p> <p>15 anything firm about heavyweights or lightweights</p> <p>16 because the fact is that the model to a study have not</p> <p>17 been found.</p> <p>18 Q. (By Mr. De La Cerda) Okay. And so your</p> <p>19 opinion is that it doesn't need to be included in</p> <p>20 the IFU; right?</p> <p>21 A. No, I don't think that has any -- any place</p> <p>22 in the IFU.</p> <p>23 Q. And your basis for that is what? I don't</p> <p>24 want to put words in your mouth.</p>	<p>1 levels of peroxide.</p> <p>2 Q. (By Mr. De La Cerda) Well, as a physician</p> <p>3 you know that the human body produces hydrogen</p> <p>4 peroxide as part of the inflammatory process; right?</p> <p>5 A. I just have not seen a quantitative assay of</p> <p>6 it.</p> <p>7 Q. Okay. So you know it happens, you just</p> <p>8 don't know what quantitatively it amounts to; right?</p> <p>9 A. I'm not aware of any quantitative study.</p> <p>10 Q. And the implantation of the TVT, TVT-O,</p> <p>11 Gynemesh, Prolift and Prosima causes an inflammatory</p> <p>12 process; correct?</p> <p>13 A. The inflammatory process being defined as a</p> <p>14 cellular process.</p> <p>15 Q. Should the fact that raw polypropylene that</p> <p>16 goes into making the Prolene, the TVT, the TVT-O,</p> <p>17 Gynemesh, Prolift and Prosima is incompatible with</p> <p>18 peroxides according to the MSDS, should that</p> <p>19 information be included in the IFU?</p> <p>20 MR. SNELL: Form.</p> <p>21 A. No, it should not be included and based --</p> <p>22 no, it shouldn't be included.</p> <p>23 Q. (By Mr. De La Cerda) You already know my</p> <p>24 next question.</p>

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<p>1 What's the basis for not including that</p> <p>2 information?</p> <p>3 A. No raw material is being asserted on humans.</p> <p>4 Q. Okay. Anything else?</p> <p>5 A. No.</p> <p>6 Q. Okay. You're also -- you addressed this in</p> <p>7 your report. You're also aware that the MSDS states:</p> <p>8 "Polypropylene has been tested in laboratory rats by</p> <p>9 subcutaneous implantation of disks or powder, local</p> <p>10 sarcomas were induced at the site of implantation."</p> <p>11 Do you recall that verbiage that's from the</p> <p>12 MSDS?</p> <p>13 A. From the MSDS.</p> <p>14 Q. What does -- what does that verbiage mean?</p> <p>15 A. It's a disk, it's a disk of basically raw</p> <p>16 polypropylene. And the way I see it is there are two</p> <p>17 factors to it. Number one, the size and the volume of</p> <p>18 the polypropylene that's being inserted, in addition</p> <p>19 to the nature of this polypropylene. I cannot speak</p> <p>20 about this being even remotely similar to what we use</p> <p>21 on -- on TVT-O and what we use in Prolene sutures</p> <p>22 because there is not -- there has been no</p> <p>23 chromatography, no crystallinity assays, no</p> <p>24 temperature assays on any of this disk. So I don't</p>	<p>1 second.</p> <p>2 You're aware of no test performed by Ethicon</p> <p>3 to determine whether the surface cracking or</p> <p>4 degradation, or whatever you want to call it, that's</p> <p>5 been -- that is seen under -- under microscope of the</p> <p>6 mesh, whether it's biofilm or whatever you believe it</p> <p>7 is, you've never seen a test by Ethicon to determine</p> <p>8 whether that particular characteristic is clinically</p> <p>9 significant to patients; right?</p> <p>10 A. No, there are only three reports that I'm --</p> <p>11 that I'm aware of.</p> <p>12 Q. Okay. And you're aware of no test by</p> <p>13 Ethicon to determine whether the weight of Prolene</p> <p>14 mesh causes more complications in patients in</p> <p>15 comparison to lightweight mesh; correct?</p> <p>16 MR. SNELL: Form, foundation.</p> <p>17 A. There's no -- no basis to generate that --</p> <p>18 that study.</p> <p>19 Q. (By Mr. De La Cerda) What do you mean by</p> <p>20 that?</p> <p>21 A. No one has come out with the actual question</p> <p>22 in terms -- in the question on the hypothesis of it or</p> <p>23 the theory of it.</p> <p>24 Q. Okay.</p>
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<p>1 have that information available.</p> <p>2 That being said, you can also consider --</p> <p>3 you should also consider the host in which most of the</p> <p>4 time is Wistar rats, Wistar rats or Himalayan rabbits.</p> <p>5 I had the opportunity to work with Wistar rats. They</p> <p>6 have a very, very peculiar immune system.</p> <p>7 Q. When there is an indication that a substance</p> <p>8 can cause cancer in animals, like rats, what does that</p> <p>9 possibly indicate for humans?</p> <p>10 MR. SNELL: Form, speculation.</p> <p>11 A. It has very, very little implications unless</p> <p>12 you are consistently prove that these causes -- causes</p> <p>13 cancer.</p> <p>14 Now, this is -- these are -- it's very</p> <p>15 important to define that these are two different</p> <p>16 materials. The raw preparations are different from</p> <p>17 the preparations used in -- in sutures. They're two</p> <p>18 different things.</p> <p>19 Q. (By Mr. De La Cerda) Chronic inflammation</p> <p>20 has been linked to cancer; hasn't it?</p> <p>21 A. That's -- that's not even a theory. That's</p> <p>22 a hypothesis, actually.</p> <p>23 Q. Okay. If mesh -- strike that.</p> <p>24 Ethicon -- I need to go back for just a</p>	<p>1 A. In other words, just because we think that</p> <p>2 there's a scientific study that we can do doesn't mean</p> <p>3 that that needs to be done.</p> <p>4 Q. Okay. But Ethicon -- Ethicon, itself,</p> <p>5 hasn't performed that study; right?</p> <p>6 A. I -- I am -- I am not familiar with the</p> <p>7 specific studies that they have performed on that</p> <p>8 specific area.</p> <p>9 Q. You're aware of no study performed by</p> <p>10 Ethicon to determine whether polypropylene could be</p> <p>11 linked to cancer; right?</p> <p>12 A. I -- I am not familiar of that, but I know</p> <p>13 about the dog study that -- in which they -- sutures</p> <p>14 were evaluated at about eight years and there was</p> <p>15 no -- no reported cancer that I'm aware of.</p> <p>16 Q. Okay. You brought one study with you here.</p> <p>17 I think it was a case report of cancer and</p> <p>18 polypropylene. What was it? You mentioned it briefly</p> <p>19 when we were looking through your materials.</p> <p>20 A. It is -- the first case reported of a clear</p> <p>21 cell carcinoma in the surrounding area to the -- to</p> <p>22 the incision for the midurethral sling.</p> <p>23 I also brought the response from two experts</p> <p>24 to that specific case report.</p>

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<p>1 Q. What did that study -- did that study have</p> <p>2 some sort of conclusion about what might be causing</p> <p>3 that clear cell carcinoma?</p> <p>4 A. No, it does not have a conclusion. There's</p> <p>5 a hypothesis and that's as far as they can get about a</p> <p>6 hypothesis about inflammation, I believe.</p> <p>7 Q. And so that's one discussion of inflammatory</p> <p>8 process being at least hypothesized as being</p> <p>9 responsible for this particular cancer; right?</p> <p>10 A. Yeah, unfort- -- I don't want to say</p> <p>11 unfortunately, it's not unfortunate. It's -- this is</p> <p>12 not an actual study. This is a case report.</p> <p>13 Q. Case report.</p> <p>14 A. One case report. And as we have gone</p> <p>15 through so many times today, the overwhelming data --</p> <p>16 there are papers that -- there are articles that</p> <p>17 describe the continued use of polypropylene in</p> <p>18 midurethral sling with the incidence of cancer in that</p> <p>19 population or the frequency of cancer in that</p> <p>20 population being actually zero.</p> <p>21 Q. Okay. So then the question about your</p> <p>22 opinion, should this warning that's included in the</p> <p>23 MSDS -- or this verbiage that's included in the MSDS</p> <p>24 regarding the subcutaneous implant of disk or powder</p>	<p>1 A. I -- I -- I'll have to read that. If you</p> <p>2 can be blinded to your study, that would be optimal,</p> <p>3 but that's not possible in every -- in every design.</p> <p>4 Q. So are you saying that a scientist in a</p> <p>5 re- -- scientist and a physician -- it's okay for</p> <p>6 that -- strike that.</p> <p>7 It's okay for a scientist and a physician to</p> <p>8 go into a research study with the desire to achieve a</p> <p>9 specific result?</p> <p>10 A. No, I think that the design of the study</p> <p>11 would actually protect the study from any desire that</p> <p>12 anyone could have.</p> <p>13 Q. So should or should not the scientist and</p> <p>14 the physician go into a study with the desire to</p> <p>15 achieve a specific result?</p> <p>16 MR. SNELL: Form, overbroad.</p> <p>17 A. I don't -- I don't believe that anyone</p> <p>18 should go into any study hoping or wishing for a</p> <p>19 specific result. That's not what the methodology of a</p> <p>20 science is for.</p> <p>21 Q. (By Mr. De La Cerda) You agree that a</p> <p>22 scientist and a physician should not design a</p> <p>23 research project for medical publication with the</p> <p>24 specific purpose of a single result; correct?</p>
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<p>1 where local carcinomas were induced at the site of</p> <p>2 implantation, should that information be included in</p> <p>3 the IFUs for the TVT, the TVT-O, Gynemesh, Prolift and</p> <p>4 Prosima?</p> <p>5 A. The answer is no, and the basis of that is</p> <p>6 that is not relevant to the product that is being</p> <p>7 implanted.</p> <p>8 Q. Has -- are you aware of any studies that</p> <p>9 Ethicon's done comparing the raw polypropylene with</p> <p>10 the manufactured version that is actually implanted in</p> <p>11 humans, any test of any kind?</p> <p>12 A. Raw -- raw polypropylene is not used in</p> <p>13 humans. Raw polypropylene is actually not even used</p> <p>14 on containers. It has very -- it doesn't have an</p> <p>15 actual use. It's raw material.</p> <p>16 Q. And so you're aware of no studies, though,</p> <p>17 where Ethicon's tested raw polypropylene versus the</p> <p>18 finished manufactured product of any type; right?</p> <p>19 A. No, I'm not familiar with any studies using</p> <p>20 raw polypropylene.</p> <p>21 Q. Okay. Shifting gears a little bit.</p> <p>22 You agree that as a scien- -- a scientist or</p> <p>23 a physician should not go into a research study with a</p> <p>24 desire to achieve a specific result; correct?</p>	<p>1 MR. SNELL: Form.</p> <p>2 A. It's -- there's no science if you are trying</p> <p>3 to get it or achieve a specific result.</p> <p>4 Q. (By Mr. De La Cerda) You can't go into a</p> <p>5 medical scientific research trying to answer a</p> <p>6 question with any preconceived biases; right?</p> <p>7 MR. SNELL: Form, overbroad.</p> <p>8 A. There's -- we -- we have seen that there --</p> <p>9 there's some preconceived biases, but they become</p> <p>10 clearly evident.</p> <p>11 Q. (By Mr. De La Cerda) But you shouldn't go</p> <p>12 in with any preconceived biases, that's what you</p> <p>13 shouldn't do; right?</p> <p>14 A. You don't -- you don't do that as a</p> <p>15 scientist.</p> <p>16 Q. Right. Do you agree it's not ethical for</p> <p>17 researchers performing clinical trials to be paid if</p> <p>18 and only if the clinical trials have certain results?</p> <p>19 MR. SNELL: Form, overbroad.</p> <p>20 Go ahead.</p> <p>21 A. I have no basis to judge anyone that has</p> <p>22 good science, good knowledge, and to be compensated</p> <p>23 for it.</p> <p>24 Q. (By Mr. De La Cerda) No, and I -- well,</p>

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<p>1 that's excellent, but my question is a little 2 different. 3 What I'm saying is whether you believe it's 4 ethical for researchers performing clinical trials to 5 be paid if and only if they produce a study with 6 specific results. 7 MR. SNELL: Same objection. 8 Q. (By Mr. De La Cerda) So not the fact 9 they're being paid, just the fact they only get paid 10 if you give me these results? 11 A. Well, it's -- you're going -- if I'm going 12 to acquire a product from you, and I'm going to make 13 an investment on that product, I'm going to pay you 14 based on what you show me with your -- with your 15 product. 16 Now, you can -- you can actually do that. 17 You can sell me a product that may not perform as I 18 expect, but if I try that product and I see that 19 consistently works in ways that are the same or better 20 as you present it, you can go back and say that was 21 not an issue there. 22 Q. Okay. So you can go back in time and say it 23 was okay, it wasn't unethical to do that? 24 A. It's -- you can go back in time and say it's</p>	<p>1 Q. And you've seen the Ulmsten and Nilsson 2 studies that Ethicon touts as long-term support for 3 their TVT line of slings; right? 4 MR. SNELL: Form. 5 A. They also wasn't just the inventor of the 6 TVT. At that time he brought the most innovative kind 7 of approach to incontinence. I mean, we -- we were -- 8 until that time, we were doing continence procedures 9 in the urethrovesical junction, we were using sutures, 10 we were placing things under tension, we were using 11 absorbable materials that didn't work long term, 12 materials that were not pliable and they came up and 13 changed the way we were thinking about continence 14 care. Continence care became different because of 15 Ulmsten and Petros. 16 Q. (By Mr. De La Cerda) Getting back to the 17 question. You've seen the studies that Ethicon 18 touts as support for their TVT line of slings; 19 right? You've seen those, the Ulmsten/Nilsson 20 studies; right? 21 MR. SNELL: Form. 22 Go ahead. 23 A. I've seen the Ulmsten studies, I've seen 24 Nilsson, I've seen Falconer, I've seen Petros.</p>
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<p>1 not a matter of ethical or not ethical. I know that 2 there was a truth -- a truthful interaction and that 3 what this physician or anyone in that calculating 4 innovation shows me was -- was real, was actually 5 accurate. 6 Q. Okay. You mean that you can at least agree 7 that that has a potential to create bias, doesn't it, 8 in the study? 9 A. I -- but you can -- you cannot put that on 10 the person that is trying to bring it in. There has 11 to be a level of -- of understanding and backtracking. 12 In other words, if you -- and I'm going to 13 allow myself to place an example. If you try to sell 14 me a medical device, I will have a hard time buying it 15 from you. But when -- if you try to sell me a legal 16 product, I might be more attracted to buy from you and 17 I might believe that you may deliver that legal 18 product. 19 That has nothing to do with science. I 20 deviated into what -- just to illustrate a point just 21 to answer your question. 22 Q. You're aware, of course, that Ulmsten was 23 the inventor of original TVT; right? 24 A. Yes.</p>	<p>1 Q. (By Mr. De La Cerda) You've seen it in 2 the marketing materials for Ethicon that they 3 frequently site to those studies as being support 4 for the use of their slings; right? 5 A. For that -- for that specific use, yes. 6 Q. And you've relied on these studies to 7 support your practice of using the TVT line of 8 products; right? 9 A. I rely on that and I rely more than that on 10 large studies. And the fact is that it has been 11 reproduced over and over again. 12 Q. Did Ethicon ever inform you that Professor 13 Ulmsten's company, MedScan, the company that owned the 14 rights to the TVT, was promised \$400,000 if and only 15 if it produced a study with the TVT showing certain 16 results? 17 MR. SNELL: Form. 18 A. There's my interaction with -- or any 19 surgeon's interaction for that sake at that time, 20 would never get into that. 21 Q. (By Mr. De La Cerda) So you haven't heard 22 that? 23 A. No, I -- I saw -- I saw that as one of the 24 claims, through all these documents, but really</p>

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<p style="text-align: right;">Page 210</p> <p>1 didn't -- didn't matter much to me.</p> <p>2 Q. Okay. So that particular fact doesn't</p> <p>3 matter to you?</p> <p>4 A. No.</p> <p>5 Q. Okay. Shifting gears a little bit. Should</p> <p>6 a medical device company put profits above patient</p> <p>7 safety?</p> <p>8 MR. SNELL: Form, speculation.</p> <p>9 THE COURT REPORTER: I'm sorry, form --</p> <p>10 MR. SNELL: Form, speculation. Put</p> <p>11 overbroad in there, too.</p> <p>12 A. Safety and results bring you profits.</p> <p>13 Q. (By Mr. De La Cerda) So is the answer no?</p> <p>14 A. No.</p> <p>15 Q. Should a medical device company rush a</p> <p>16 product to market with the primary purpose being to</p> <p>17 defend its market share?</p> <p>18 A. There's -- when you have a good product and</p> <p>19 you have enough market share, yeah, you want to make</p> <p>20 sure that you keep it and you keep it with quality.</p> <p>21 Q. So the answer is yes to that one?</p> <p>22 MR. SNELL: Form.</p> <p>23 A. On that one -- on that regard, on the</p> <p>24 general form of that question, yes.</p>	<p style="text-align: right;">Page 212</p> <p>1 submitted. I cannot recall it right now. I can go</p> <p>2 back and check what was submitted, but I'm not</p> <p>3 familiar with it.</p> <p>4 Q. If he had performed a study, do you believe</p> <p>5 that that study should have been submitted along with</p> <p>6 the information about the TVT-O to the FDA?</p> <p>7 MR. SNELL: Form, calls for regulatory</p> <p>8 opinion, outside the regulatory scope.</p> <p>9 A. I think it goes to whatever -- whatever the</p> <p>10 FDA feels that it requires from the company or</p> <p>11 whatever the company fulfills in its obligations to</p> <p>12 the FDA.</p> <p>13 Q. (By Mr. De La Cerda) How about you as a</p> <p>14 physician, before you're going to use a product,</p> <p>15 would you want to know all the clinical studies that</p> <p>16 are out there about that product before you start</p> <p>17 implanting it?</p> <p>18 A. I actually gave -- I have given testimony</p> <p>19 today that I trust that the FDA is going to do what's</p> <p>20 best in that regard.</p> <p>21 Q. Do you have any understanding of what the</p> <p>22 clearance process involves, 510(k) clearance?</p> <p>23 A. Yes. I do have an understanding of it.</p> <p>24 Q. Do you know whether the FDA requires</p>
<p style="text-align: right;">Page 211</p> <p>1 Q. (By Mr. De La Cerda) What clinical</p> <p>2 studies were done of the TVT-O before it was</p> <p>3 released onto the market?</p> <p>4 A. There was -- there were a variety of</p> <p>5 studies. There was the Mulberry study --</p> <p>6 THE COURT REPORTER: The --</p> <p>7 THE WITNESS: The Mulberry.</p> <p>8 A. -- and there was -- there were cadaver</p> <p>9 studies, and there were studies on outside-in</p> <p>10 transobturator slings.</p> <p>11 Q. Was one of the studies by de Leval?</p> <p>12 A. By Delorme first and then de Leval.</p> <p>13 Q. Delorme was outside-in; right?</p> <p>14 A. Right.</p> <p>15 Q. And then de Leval was inside-out?</p> <p>16 A. Right.</p> <p>17 Q. De Leval is considered the inventor of the</p> <p>18 TVT-O; is that right?</p> <p>19 A. Yes.</p> <p>20 Q. And do you know whether the results of</p> <p>21 de Leval's clinical studies were included in the</p> <p>22 application for clearance submitted to the FDA for the</p> <p>23 TVT-O?</p> <p>24 A. I'm not familiar with what was exactly</p>	<p style="text-align: right;">Page 213</p> <p>1 clinical studies before a product is 510(k) cleared?</p> <p>2 A. I think that they have made -- I don't</p> <p>3 think, I'm aware that they have made a decision to put</p> <p>4 in place a mechanism that works exactly with a 510(k).</p> <p>5 Now, am I someone to criticize or favor --</p> <p>6 or favor that? I probably could sit in my big chair</p> <p>7 and decide that, but the reality is that there's</p> <p>8 people with expertise in regulatory affairs at the FDA</p> <p>9 and people with expertise on regulatory affairs at</p> <p>10 Ethicon, and they're the ones that need to come</p> <p>11 together on that.</p> <p>12 Q. I guess the issue that I'm really asking</p> <p>13 about is what you want to know as a doctor. Before</p> <p>14 you ever implant a product, do you want to know that</p> <p>15 if there are clinical studies on that product before</p> <p>16 you've implanted it, do you want to know what those</p> <p>17 clinical -- what the findings were of those clinical</p> <p>18 studies before you implant the product?</p> <p>19 A. I'm aware of clinical products and design.</p> <p>20 I'm aware of these studies, but you can present all</p> <p>21 these studies and one final part is going to be what</p> <p>22 the FDA regulatory process comes -- comes and tells</p> <p>23 me.</p> <p>24 Q. What I'm saying, though, is you, as an</p>

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<p style="text-align: right;">Page 214</p> <p>1 implanting physician, okay, a product is presented to</p> <p>2 you by a medical device company and there are clinical</p> <p>3 studies out there that are about this particular</p> <p>4 product. You're going to want to know all the</p> <p>5 clinical studies that are out there about that product</p> <p>6 before you implant it; right?</p> <p>7 MR. SNELL: Form, asked and answered.</p> <p>8 Go ahead.</p> <p>9 A. I want to know -- I want to know the studies</p> <p>10 and I want to know -- obviously, I want to know more</p> <p>11 than just the studies. I want to know the</p> <p>12 biomechanics of it, I want to know all these things.</p> <p>13 But that's -- ultimately, it comes down to that</p> <p>14 process between the -- between Ethicon and the FDA.</p> <p>15 Q. (By Mr. De La Cerda) Okay.</p> <p>16 A. And I'm going to trust the product that</p> <p>17 comes out from it.</p> <p>18 Q. Okay. Let's shift gears a little bit.</p> <p>19 You're aware that the IFUs for the Gynemesh,</p> <p>20 Prolift and Prosima state: "The mesh remains soft and</p> <p>21 pliable and normal wound healing is not noticeably</p> <p>22 impaired"; right?</p> <p>23 MR. SNELL: Foundation on that.</p> <p>24 Do you have that IFU? I'm not sure if you</p>	<p style="text-align: right;">Page 216</p> <p>1 enzymes."</p> <p>2 Q. (By Mr. De La Cerda) So that statement is</p> <p>3 included, of course, in the Gynemesh IFU and the</p> <p>4 Prolift and Prosima IFUs, which also use Gynemesh;</p> <p>5 right?</p> <p>6 A. Yes.</p> <p>7 Q. Now, you're aware that Gynemesh PS is</p> <p>8 Prolene Soft, except for it's used in the pelvic</p> <p>9 application as opposed to hernia application; right?</p> <p>10 A. It's -- Pro- -- Prolene Soft, yes.</p> <p>11 Q. Are you aware that in 2001, Ethicon had in</p> <p>12 its files a conclusion that Gynemesh PS was too stiff</p> <p>13 for use in vaginal tissues?</p> <p>14 MR. SNELL: Form, foundation.</p> <p>15 A. It's -- I read something about that from</p> <p>16 some investigator, but it was -- it was an opinion</p> <p>17 about being too stiff. I think it was at the -- at</p> <p>18 the risk of -- I'm not remembering well or -- I'm not</p> <p>19 speaking accurately, may have been an investigator's</p> <p>20 opinion.</p> <p>21 Q. (By Mr. De La Cerda) Okay. Are you aware</p> <p>22 that Ethicon also had in its files a conclusion that</p> <p>23 Prolene Soft should not be pursued as a mesh used in</p> <p>24 pelvic floor repair because it was too stiff for use</p>
<p style="text-align: right;">Page 215</p> <p>1 made a correct statement across all those IFUs.</p> <p>2 Do you mind taking a break?</p> <p>3 MR. DE LA CERDA: That's fine. Let's do</p> <p>4 that.</p> <p>5 (Thereupon, a recess was taken from</p> <p>6 2:11 p.m. until 2:18 p.m., after which the</p> <p>7 following proceedings were held:)</p> <p>8 Q. (By Mr. De La Cerda) Doctor, just for the</p> <p>9 sake of showing you, this is the Gynemesh -- sorry,</p> <p>10 I didn't bring a copy of it -- so that's the</p> <p>11 Gynemesh IFU. The part that I'm referencing is at</p> <p>12 the bottom, I think it's the second-to-last</p> <p>13 sentence. It starts with "the mesh remains</p> <p>14 pliable."</p> <p>15 MR. SNELL: Soft and pliable.</p> <p>16 Why don't you ask him to read it just so the</p> <p>17 record is clear.</p> <p>18 MR. DE LA CERDA: Yeah, sure.</p> <p>19 Q. (By Mr. De La Cerda) Can you read that,</p> <p>20 Doctor?</p> <p>21 A. "The mesh remains soft and pliable and</p> <p>22 normal wound healing is not noticeably impaired. The</p> <p>23 material is not absorbed, nor is subject to</p> <p>24 degradation or weakening by the action of tissue</p>	<p style="text-align: right;">Page 217</p> <p>1 in vaginal tissues?</p> <p>2 MR. SNELL: Same objection.</p> <p>3 A. No, I'm not -- I'm not aware of that and</p> <p>4 that's not what was eventually done.</p> <p>5 Q. (By Mr. De La Cerda) Do you know whether</p> <p>6 scar contracture around the mesh can occur with the</p> <p>7 Gynemesh?</p> <p>8 A. There's -- there's -- there's this -- again,</p> <p>9 hypothesis that scar contraction could happen around</p> <p>10 the mesh. So to that -- to that specific issue, I ask</p> <p>11 what is the objective measurement of a scar</p> <p>12 contraction or the mesh contraction. I wanted to see</p> <p>13 where -- where's the evidence to it?</p> <p>14 Because when we repair these -- repair these</p> <p>15 patients with permanent sutures, when we place</p> <p>16 polypropylene in the uterosacral ligaments or in the</p> <p>17 sacrospinous ligament, we didn't see any contraction</p> <p>18 of those fibers. So where is the evidence? No one</p> <p>19 could ever bring me evidence of a contraction on the</p> <p>20 mesh.</p> <p>21 Q. Okay. Do you know if that -- if this scar</p> <p>22 contracture around Gynemesh was a problem that Ethicon</p> <p>23 engineers were trying to solve?</p> <p>24 A. I -- I don't even know if they try to solve</p>

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<p>1 it because I did not see a problem with contraction.</p> <p>2 Q. Okay. So you're also not sure, though,</p> <p>3 whether Ethicon was trying to solve this problem? You</p> <p>4 probably don't believe it's a problem. That's what it</p> <p>5 sounds like you're saying, that it's not a problem,</p> <p>6 but my question is really are you aware whether</p> <p>7 Ethicon was trying to solve what it perceived to be a</p> <p>8 problem with contracture of scar tissue around</p> <p>9 Gynemesh?</p> <p>10 MR. SNELL: Foundation.</p> <p>11 A. I don't -- I don't see in which model they</p> <p>12 would try to solve it.</p> <p>13 Q. (By Mr. De La Cerda) Okay. But are you</p> <p>14 aware if they were trying to solve this or not?</p> <p>15 A. No, I'm not aware of them trying to solve</p> <p>16 contractions of any -- any type, any type of implants.</p> <p>17 Q. If scar contracture exists around Gynemesh,</p> <p>18 would that translate into complications for a patient?</p> <p>19 MR. SNELL: Form.</p> <p>20 A. More than a complication for a patient. The</p> <p>21 contraction would just tell me that I have to -- I</p> <p>22 have to make adjustments in my surgery and that brings</p> <p>23 a whole new set of variables in my -- in my surgery.</p> <p>24 Q. (By Mr. De La Cerda) Do you know whether</p>	<p>1 MR. SNELL: Actually, hold on. Objection,</p> <p>2 foundation, misstates company intent.</p> <p>3 A. I don't -- I don't think that that's what</p> <p>4 they concluded, that it was safer. I don't think that</p> <p>5 there is anyone that actually came and say, "Okay,</p> <p>6 this is safer," or, "We have more evidence to say that</p> <p>7 it's safer, but you may have to adjust it," or "It may</p> <p>8 not contract or they will contract." I don't -- I</p> <p>9 don't think it got to that point. I think that we had</p> <p>10 what we had with Gynemesh.</p> <p>11 Q. (By Mr. De La Cerda) Okay. Did you ever</p> <p>12 do a presentation on the benefits of lightweight</p> <p>13 mesh over heavyweight mesh?</p> <p>14 A. I did make presen- -- many presentations on</p> <p>15 how -- on the benefits of lightweight mesh, and that</p> <p>16 was a prevailing -- the prevailing thought at that</p> <p>17 time and I still would make a presentation and say</p> <p>18 there are some benefits on lightweight mesh. There</p> <p>19 are -- there's some benefits on having less implant,</p> <p>20 in having less mesh.</p> <p>21 The question is when we have all this -- all</p> <p>22 these different -- different things that we wish for,</p> <p>23 how much science do I have behind it? And during</p> <p>24 those -- those presentations, there's always the</p>
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<p>1 or not physicians were asking Ethicon for a mesh</p> <p>2 which would be better than Gynemesh on the issue of</p> <p>3 scar contracture?</p> <p>4 A. I -- I believe that there was always the --</p> <p>5 the idea that we could always have innovation on the</p> <p>6 type of implants that we would have. Although</p> <p>7 Gynemesh had more evidence than any other implant.</p> <p>8 There was more evidence, there are more papers</p> <p>9 published on Gynemesh than native tissue for specific</p> <p>10 compartments. We have that. We all -- we all did</p> <p>11 have an understanding that there was going to be a</p> <p>12 progression on the innovation of the product. So if</p> <p>13 there is a course to do that, that's -- that's</p> <p>14 something that I think every physician would want to</p> <p>15 see.</p> <p>16 Q. And Ethicon did that -- they did just that,</p> <p>17 didn't they?</p> <p>18 A. They -- they actually invited me and give</p> <p>19 me -- with other doctors, tell me what -- what this --</p> <p>20 what would you like to see in -- in the next</p> <p>21 generation.</p> <p>22 Q. They innovated so well that they even</p> <p>23 developed a mesh, other than Gynemesh, that they</p> <p>24 thought was safer than Gynemesh; right?</p>	<p>1 discussion of: Is this really what we want? Do we</p> <p>2 want bigger pores? Do we want a lighter --</p> <p>3 lightweight meshes? Do we want lighter meshes?</p> <p>4 I'm not saying that it's going to be a bad</p> <p>5 thing. It's probably going to be a good thing, but I</p> <p>6 don't have the science to back it up.</p> <p>7 Q. You mentioned that you did present on some</p> <p>8 of the benefits of lightweight mesh or using less</p> <p>9 mesh. What would those benefits be?</p> <p>10 A. It's a -- the benefits is that you have less</p> <p>11 inflammatory response, you have less cellular</p> <p>12 response, you have a better layout of fibroblast and</p> <p>13 that's the hypothesis behind all this.</p> <p>14 But none of those things that we, as a</p> <p>15 group, thought as -- as physicians thought that was</p> <p>16 going to be better, wasn't necessarily going to be</p> <p>17 better. These were things that were not statements.</p> <p>18 These were things that we have it here and we have</p> <p>19 this product and it's worth looking to it and it's</p> <p>20 worth using it and, you know, if I'm going to have --</p> <p>21 use something heavier or something light, I probably</p> <p>22 go with something light because it's more innovative.</p> <p>23 Q. It's a reasonable theory to believe that the</p> <p>24 lightweight mesh is safer for a patient than the</p>

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<p>1 heavyweight mesh; right?</p> <p>2 A. No. That's not --</p> <p>3 MR. SNELL: Lacks foundation.</p> <p>4 Go ahead.</p> <p>5 A. No. That's not what we can conclude with</p> <p>6 it. We're not talking -- Gynemesh proved to be safe.</p> <p>7 Gynemesh proved to be effective. This is a totally</p> <p>8 different set of considerations, scientifically it's a</p> <p>9 totally different set of considerations.</p> <p>10 Q. (By Mr. De La Cerda) Let's do it this</p> <p>11 way. What I want to do is work from possibility all</p> <p>12 the way up to truth. Okay?</p> <p>13 Possibility, hypothesis, theory and we'll</p> <p>14 just say reality or truth. Okay?</p> <p>15 Is it possible -- do you agree it's possible</p> <p>16 that lightweight mesh is safer for patients than</p> <p>17 heavyweight mesh?</p> <p>18 MR. SNELL: Calls for speculation.</p> <p>19 A. That's -- that's possible.</p> <p>20 Q. (By Mr. De La Cerda) Okay. Now let's</p> <p>21 take the next step.</p> <p>22 Would it be a fair hypothesis that</p> <p>23 lightweight mesh is safer than heavyweight mesh?</p> <p>24 A. That's a hypothesis, period. Not fair, not</p>	<p>1 as explored as is being explored now. And based on --</p> <p>2 on those concepts that were unexplored, we made</p> <p>3 inferences on how we would like the next mesh to be.</p> <p>4 That doesn't take the fact that what we had</p> <p>5 behind us was data from Gynemesh.</p> <p>6 Q. Do you agree that scar contracture can cause</p> <p>7 recurrence of prolapse? This is in terms of if scar</p> <p>8 contracture is happening around Gynemesh, can that</p> <p>9 cause recurrence of prolapse?</p> <p>10 MR. SNELL: Foundation.</p> <p>11 A. Are you talking about the same side or</p> <p>12 opposite side or just in general?</p> <p>13 Q. (By Mr. De La Cerda) In general.</p> <p>14 A. No, that's not the biggest factor on a</p> <p>15 recurrence of a prolapse.</p> <p>16 Q. I'm just going to go through a little list</p> <p>17 right here.</p> <p>18 Do you agree that scar contracture around</p> <p>19 Gynemesh can cause pain?</p> <p>20 A. Contractions of scarring always have the</p> <p>21 potential to decrease the pliability of not only a</p> <p>22 mesh augmented repair but of any -- any repair.</p> <p>23 Q. That was actually going to be my next</p> <p>24 question.</p>
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<p>1 unfair, it's just a hypothesis that we would have to</p> <p>2 test.</p> <p>3 Q. Okay. Is it a fair -- based on what you</p> <p>4 know, is that a hypothesis that could be confirmed?</p> <p>5 A. Well, that's a hypothesis that has much less</p> <p>6 evidence behind it than -- than using Gynemesh.</p> <p>7 Q. The step where you would stop the</p> <p>8 progression, though, would be a theory. You don't</p> <p>9 believe there's enough to support the theory that</p> <p>10 lightweight mesh is safer for patients than</p> <p>11 heavyweight mesh; is that right?</p> <p>12 A. These were -- these were considerations that</p> <p>13 were entertained not at that time. They still</p> <p>14 entertain a scientific meeting. It doesn't mean that</p> <p>15 we're going to go -- go out and start using the</p> <p>16 lightest weight mesh. It doesn't mean -- because we</p> <p>17 understand meshes a lot better now as -- as</p> <p>18 physicians. As surgeons, as scientists, we understand</p> <p>19 it better.</p> <p>20 Now, we knew that what we had would -- would</p> <p>21 give durability. We knew that what we had would</p> <p>22 give -- would be a good product to use for</p> <p>23 reinforcement on augmented repairs. There was --</p> <p>24 there was some concept along the lines that were not</p>	<p>1 First of all, the pliability can lead to</p> <p>2 pain? Like reduced pliability can lead to pain in a</p> <p>3 patient; is that right?</p> <p>4 A. If there's less pliability and there are a</p> <p>5 number of factors to -- for a repair being less</p> <p>6 pliable, but if there is less pliability and the</p> <p>7 tissue is placed under -- under stress, yeah, you</p> <p>8 would -- you would feel more that it would be more</p> <p>9 pliable.</p> <p>10 Q. Could the scar contracture lead to erosion?</p> <p>11 A. No.</p> <p>12 Q. How about discomfort during sex?</p> <p>13 A. Less, less pliability could make things feel</p> <p>14 not -- not as soft, not as elastic.</p> <p>15 Q. Would you agree that for a mesh to be</p> <p>16 successfully used for the treatment of pelvic organ</p> <p>17 prolapse it should be soft and compliant with a</p> <p>18 woman's vaginal tissues?</p> <p>19 A. And that is -- that is an excellent question</p> <p>20 because I would like to define, which I didn't have to</p> <p>21 define before in the medical arena, I didn't have to</p> <p>22 define as much what soft and pliable and elastic is.</p> <p>23 I have tried to come to -- to the conclusion</p> <p>24 that there is a level of the formation of stress that</p>

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<p>1 is required. You cannot have so much deformation that</p> <p>2 the prolapse comes out, but you still have to have</p> <p>3 some firmness to your repair. In other words, you</p> <p>4 drive your car, you need your shock absorbers to give</p> <p>5 some give, to give some, but you don't want your shock</p> <p>6 absorbers to be bouncing all over the place. It would</p> <p>7 be as uncomfortable as no bouncing at all.</p> <p>8 So when I -- when I take my car for a shock</p> <p>9 absorbers check, they have something that actually</p> <p>10 measures it and they can adjust it. They can adjust</p> <p>11 the damper and give. We don't have that in the</p> <p>12 vagina.</p> <p>13 Q. Ethicon certainly never tested that issue;</p> <p>14 did they?</p> <p>15 MR. SNELL: Objection, lacks foundation.</p> <p>16 A. The vaginal pliability, I think that there</p> <p>17 was some papers about designing a device -- there was</p> <p>18 a paper, actually, Dr. Willy Davila, I believe, was</p> <p>19 testing a device for vaginal pliability; and that</p> <p>20 would be very useful in getting an actual number,</p> <p>21 getting an actual measurement that we can take from.</p> <p>22 Q. (By Mr. De La Cerda) Is that something</p> <p>23 that Ethicon did?</p> <p>24 A. No, I think -- I don't think -- I'm not</p>	<p>1 one but in two, three studies with comparing different</p> <p>2 repairs and native tissue repairs to mesh augmented</p> <p>3 repairs, the vaginal length stays exactly at the</p> <p>4 same -- at the same length.</p> <p>5 Q. (By Mr. De La Cerda) Should Ethicon's</p> <p>6 conclusion -- strike that.</p> <p>7 Should information about the concerns of</p> <p>8 physicians and at least some within Ethicon that</p> <p>9 Gynemesh was too stiff or too rigid for vaginal</p> <p>10 tissues, should that information be included in the</p> <p>11 IFU or no?</p> <p>12 MR. SNELL: Form, asked and answered.</p> <p>13 A. No, I don't think that it needed to be</p> <p>14 included and the fact is that surgeons have the</p> <p>15 options of doing augmented repairs or doing --</p> <p>16 continue doing native tissue repairs. And they will</p> <p>17 have whatever concern they may have with one or the</p> <p>18 other, they have the option of doing one or the other.</p> <p>19 No one mandated to do a mesh repair or a native tissue</p> <p>20 repair at a certain time. But if you went by the data</p> <p>21 and went by the durability and went by the evidence</p> <p>22 about -- with Gynemesh, you have -- you were empowered</p> <p>23 with information to decide one way or the other.</p> <p>24 Ethicon does not tell surgeons who --</p>
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<p>1 aware of Ethicon doing that.</p> <p>2 Q. Would you agree that clinically there may be</p> <p>3 an impact of increased rigidity with any given mesh as</p> <p>4 it may increase vaginal stiffness post-operatively</p> <p>5 with a potential to impair sexual function?</p> <p>6 A. I -- I misspoke on my last answer. I want</p> <p>7 to correct that.</p> <p>8 When I say Ethicon never -- never did that,</p> <p>9 I cannot conclude that because I'm not aware if they</p> <p>10 did or if they didn't, but I'm just -- that's what I'm</p> <p>11 aware of, that I don't know if they did or didn't.</p> <p>12 Q. That's fair.</p> <p>13 Let me go back to my question, the next</p> <p>14 question. Would you agree that clinically there may</p> <p>15 be an impact of increased rigidity with any given mesh</p> <p>16 as it may increase vaginal stiffness post-operatively</p> <p>17 with a potential to impair sexual function?</p> <p>18 MR. SNELL: Form, speculation, incomplete</p> <p>19 hypothetical.</p> <p>20 A. There's -- the papers that we have does</p> <p>21 not -- does not suggest or indicate rigidity. If</p> <p>22 there is a shrinkage or rigidity, it was not</p> <p>23 demonstrated on the measurements of total vaginal</p> <p>24 length. When you measure total vaginal length, not on</p>	<p>1 actually, they never told me, I can tell you that, and</p> <p>2 they would never tell anyone, "You have to do this</p> <p>3 repair with this type of material." And I don't think</p> <p>4 they would include that in the IFU and they would not</p> <p>5 include that on any communication because it's up to</p> <p>6 the surgeon to decide that.</p> <p>7 Q. (By Mr. De La Cerda) So would that be the</p> <p>8 basis for why that information is not -- does not</p> <p>9 need to be included in the IFU, according to your</p> <p>10 opinion?</p> <p>11 A. If the information on the -- on the IFU has</p> <p>12 to do with the product itself and if there's no</p> <p>13 evidence of the product performing one way or the</p> <p>14 other, I would not expect anyone to misrepresent it</p> <p>15 one way or the other. In other words, I don't --</p> <p>16 don't misrepresent it saying that it performs better,</p> <p>17 don't misrepresent it saying that it performs worse.</p> <p>18 Just give me what the evidence shows.</p> <p>19 Q. Would you agree that any future meshes</p> <p>20 developed by Ethicon for pelvic organ prolapse should</p> <p>21 be less rigid than Gynemesh?</p> <p>22 A. I don't -- I don't know if it's going to be</p> <p>23 any development, I don't know if it's -- it's going to</p> <p>24 be on the same rate of damage. I think that --</p>

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<p>1 THE COURT REPORTER: On the same?</p> <p>2 A. On the same rate of -- on the same rate</p> <p>3 of -- when I say "rate," on the same elasticity or</p> <p>4 pliability of Gynemesh.</p> <p>5 I don't know if it's going to be the same</p> <p>6 stiffness or not. I just don't know what they're</p> <p>7 going to do with the next generation.</p> <p>8 Q. But my question is, though, is: If they are</p> <p>9 going to develop the next generation, do you agree</p> <p>10 that that next generation should be less rigid than</p> <p>11 Gynemesh?</p> <p>12 MR. SNELL: Objection, foundation.</p> <p>13 A. I think we will have to first establish a</p> <p>14 way of rigidity in -- once in the vagina and not just</p> <p>15 on the testing that we have, biomechanical testing.</p> <p>16 We know that biomechanical testing as</p> <p>17 accurate and as elaborate and as complicated as it can</p> <p>18 be, it doesn't always predict the -- the rigidity in</p> <p>19 the vagina, because we don't know how to measure</p> <p>20 rigidity in the vagina. We don't know how you're</p> <p>21 going to measure it.</p> <p>22 Q. Let me shift gears a little bit.</p> <p>23 Okay. You understand before a medical</p> <p>24 device can be marketed in the United States, the FDA</p>	<p>1 A. Marketing -- marketing a device -- marketing</p> <p>2 a device doesn't mean that you cannot -- you cannot</p> <p>3 sell it. I don't think it has the relationship of one</p> <p>4 with the other. If you -- if marketing means someone</p> <p>5 visited me and giving me a brochure and telling me all</p> <p>6 these things about the product, I really want to look</p> <p>7 at the evidence. I will be courteous and I will</p> <p>8 listen to it, but I will go to -- with the evidence.</p> <p>9 And the evidence was, at that time and still</p> <p>10 today, that -- that the materials used were as good as</p> <p>11 a native tissue and was more durable.</p> <p>12 Q. (By Mr. De La Cerda) So you're telling me</p> <p>13 that doctors didn't need to know before they put in</p> <p>14 a Prolift if it hadn't even been cleared by the FDA</p> <p>15 until May 15, 2008?</p> <p>16 MR. SNELL: Same objections.</p> <p>17 Q. (By Mr. De La Cerda) Because there</p> <p>18 were -- there were hundreds, if not thousands, of</p> <p>19 Prolifts put in before it was ever cleared. Do you</p> <p>20 understand that?</p> <p>21 MR. SNELL: Same foundation, objection.</p> <p>22 A. I'm not -- I'm not aware of that specific --</p> <p>23 Q. (By Mr. De La Cerda) We can -- we don't</p> <p>24 even have to have a number. If one was put in</p>
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<p>1 requires that the device receive some level of</p> <p>2 clearance or approval before that marketing happens;</p> <p>3 right?</p> <p>4 A. Yes.</p> <p>5 Q. You're aware that Prolift wasn't cleared for</p> <p>6 marketing in the United States by the FDA until</p> <p>7 May 15, 2008; right?</p> <p>8 MR. SNELL: Form.</p> <p>9 A. There were some -- some dates in there, but</p> <p>10 I don't have the dates complete.</p> <p>11 Q. (By Mr. De La Cerda) You understand that</p> <p>12 Prolift was marketed in the United States for</p> <p>13 approximately three years before it received</p> <p>14 clearance. Do you understand that?</p> <p>15 MR. SNELL: Form, foundation.</p> <p>16 A. Yeah, it's -- it may have been marketed,</p> <p>17 yes. I don't -- I don't know -- I cannot give you an</p> <p>18 accurate answer on that.</p> <p>19 Q. (By Mr. De La Cerda) Should the fact that</p> <p>20 Prolift wasn't cleared for marketing in the United</p> <p>21 States been included in the Prolift IFUs in place</p> <p>22 prior to May 15, 2008?</p> <p>23 MR. SNELL: Form, foundation, misstates the</p> <p>24 regulatory --</p>	<p>1 before it was ever cleared by the FDA, do you think</p> <p>2 it's okay for a doctor to not know that it wasn't</p> <p>3 cleared by the FDA before he puts it in to a</p> <p>4 patient?</p> <p>5 MR. SNELL: Same objection.</p> <p>6 A. It had a 510(k) approval; correct?</p> <p>7 Q. (By Mr. De La Cerda) May 15, 2008. So</p> <p>8 for three years it didn't.</p> <p>9 Have you ever seen the correspondence</p> <p>10 between Ethicon and the FDA about that clearance</p> <p>11 issue?</p> <p>12 MR. SNELL: Same objection, foundation.</p> <p>13 A. I'm not aware of that, no.</p> <p>14 Q. (By Mr. De La Cerda) Are you aware of the</p> <p>15 510(k) being rejected a couple times?</p> <p>16 MR. SNELL: Actually misstates the evidence,</p> <p>17 foundation as well.</p> <p>18 Q. (By Mr. De La Cerda) You haven't seen any</p> <p>19 of that correspondence?</p> <p>20 A. Not -- not on that specific issue, no, I</p> <p>21 have not seen it.</p> <p>22 Q. All right.</p> <p>23 A. But if you give it to me, I'll check it out.</p> <p>24 I'll give an opinion on it. That's -- that's ...</p>

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<p style="text-align: right;">Page 234</p> <p>1 Q. So let's take the simple fact this product</p> <p>2 was marketed in the United States before it ever had</p> <p>3 clearance. Now, before a doctor ever implants the</p> <p>4 product, do you think it's fair for him not to know</p> <p>5 that the product he's implanting hasn't even been</p> <p>6 cleared by the FDA?</p> <p>7 MR. SNELL: Same objection, misstates the</p> <p>8 evidence and the foundation as to the clearance.</p> <p>9 A. If it's -- I don't want to give you an</p> <p>10 opinion on something that I haven't seen.</p> <p>11 Q. (By Mr. De La Cerda) As you sit here</p> <p>12 today, you have not reviewed any of the</p> <p>13 correspondence between the FDA and Ethicon regarding</p> <p>14 the clearance of the Prolift under the 510(k)</p> <p>15 process; right?</p> <p>16 A. I -- I know that Prolift was cleared and I</p> <p>17 know that there was -- the product had been sold. I</p> <p>18 just don't know the specifics of when was it cleared</p> <p>19 and the dates as you're referring to.</p> <p>20 Q. What I want to try to get at now is, as you</p> <p>21 sit here today, are you going to provide any opinions</p> <p>22 about the Prolift and the timing of its clearance and</p> <p>23 what effect that might have on warnings to doctors?</p> <p>24 A. As we sit here today, I cannot give you an</p>	<p style="text-align: right;">Page 236</p> <p>1 Out of all the plaintiff's guys you meet, I'm the</p> <p>2 nice one.</p> <p>3 MR. SPARKS: Hey.</p> <p>4 MR. DE LA CERDA: He's a nice one, too.</p> <p>5 Q (By Mr. De La Cerda) Let's switch gears a</p> <p>6 little bit.</p> <p>7 Do you agree with the FDA's viewpoint that</p> <p>8 there is a need for more rigorous studies regarding</p> <p>9 the safety and efficacy of transvaginal mesh kits?</p> <p>10 A. The --</p> <p>11 MR. SNELL: Hold on. You said -- can you</p> <p>12 read that last -- he said transvaginal --</p> <p>13 THE COURT REPORTER: Mesh kits.</p> <p>14 MR. SNELL: I'm going to object, overbroad,</p> <p>15 to the extent you're including Prolift</p> <p>16 midurethral slings.</p> <p>17 MR. DE LA CERDA: And I'm not, so I do want</p> <p>18 to be clear about that.</p> <p>19 When I'm using this term "transvaginal mesh</p> <p>20 kits," it's transvaginal mesh for the correction</p> <p>21 of pelvic organ prolapse.</p> <p>22 So let me go back. Let me read the question</p> <p>23 one more time.</p> <p>24 Q. (By Mr. De La Cerda) Do you agree with</p>
<p style="text-align: right;">Page 235</p> <p>1 opinion about something that I have not read.</p> <p>2 Q. Okay. And so you know today is my</p> <p>3 opportunity to question you about this issue. This</p> <p>4 isn't a new issue, it's been around since 2008. So if</p> <p>5 you're telling me today that you don't have -- you're</p> <p>6 not prepared to provide an opinion on that issue,</p> <p>7 that's great. That sends me down one road.</p> <p>8 If you're telling me today that you do have</p> <p>9 an opinion, then that's why -- then I would like to</p> <p>10 ask questions about it. But if you're not going to</p> <p>11 opine -- if you don't intend to opine on the effect of</p> <p>12 the timing of the clearance of the Prolift through the</p> <p>13 510(k) process and that effect on what should be</p> <p>14 warned or what should be told to doctors about the</p> <p>15 Prolift, then that's fine and we can move on to the</p> <p>16 next subject.</p> <p>17 A. No, I can -- I can look at those papers and</p> <p>18 I cannot give you an opinion at this time about papers</p> <p>19 that I have not seen.</p> <p>20 Q. Are those papers in your Reliance List?</p> <p>21 A. No, I don't think they're in my Reliance</p> <p>22 List. If they would be, I would have read it.</p> <p>23 THE WITNESS: Oh, you didn't --</p> <p>24 MR. DE LA CERDA: I'm actually the nice one.</p>	<p style="text-align: right;">Page 237</p> <p>1 the FDA's viewpoint that there is a need for more</p> <p>2 rigorous studies regarding the safety and efficacy</p> <p>3 of transvaginal mesh kits, meaning transvaginal mesh</p> <p>4 for the correction of pelvic organ prolapse?</p> <p>5 A. No, I disagree with that recommendation.</p> <p>6 Q. (By Mr. De La Cerda) Okay. And why is it</p> <p>7 that you disagree?</p> <p>8 A. I disagree because there was a wealth of</p> <p>9 data on -- on the use of transvaginal mesh that has</p> <p>10 been determined by more than 400 surgeons -- 400</p> <p>11 active surgeons that it was adequate.</p> <p>12 The decision of the FDA, with all due</p> <p>13 respect to the organization or to whoever put the time</p> <p>14 and put their effort in sitting on that committee, did</p> <p>15 not -- did not translate on or did not convey the</p> <p>16 experience of all the surgeons.</p> <p>17 Q. Did you ever actually see the FDA's 522</p> <p>18 orders that were issued with regard to Gynemesh,</p> <p>19 Prolift and Prosima?</p> <p>20 A. I did -- I did read about those, yes.</p> <p>21 Q. Do you know what these orders required of</p> <p>22 Ethicon?</p> <p>23 A. Yes. I -- I read about the requirements and</p> <p>24 I also read at one time the response of Ethicon to the</p>

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<p>1 FDA.</p> <p>2 Q. That was my next question. Do you know what</p> <p>3 is it that Ethicon did in response to the 522 orders?</p> <p>4 A. They -- they made a statement along the</p> <p>5 lines of what I just mentioned, that there were</p> <p>6 studies, not only RCTs, not only -- but also cohort</p> <p>7 studies that show the benefits in durability, it</p> <p>8 showed the safety profile, it showed risk and</p> <p>9 complications, very well delineated in ways that no</p> <p>10 other repair had been addressed.</p> <p>11 Q. Did you also see any information regarding</p> <p>12 Ethicon's estimate on the cost to have complied with</p> <p>13 the 522 orders?</p> <p>14 A. I did not see the exact cost, but I know</p> <p>15 that any -- any study is costly.</p> <p>16 Q. And Ethicon ultimately decided not to</p> <p>17 perform what was discussed within the 522 orders;</p> <p>18 correct?</p> <p>19 A. That's -- that's what I -- I -- I saw from</p> <p>20 the -- from that process, from that specific process.</p> <p>21 Q. Ultimately, Ethicon decided to pull those</p> <p>22 products from the market; right? Prolift and Prosima</p> <p>23 were pulled from the market; correct?</p> <p>24 A. Yes.</p>	<p>1 called "decommercialization" and labeled that as</p> <p>2 what it did for the Prolift and the Prosima, point</p> <p>3 is ultimately Prolift and Prosima they stopped</p> <p>4 selling; right?</p> <p>5 MR. SNELL: Form, predicate.</p> <p>6 A. Yes.</p> <p>7 Q. (By Mr. De La Cerda) Gynemesh they</p> <p>8 changed the indication; right?</p> <p>9 A. That's -- yeah, I became aware of that.</p> <p>10 Q. And that avoided Ethicon having to comply</p> <p>11 with the studies required in the 522 orders; correct?</p> <p>12 MR. SNELL: Objection, speculation.</p> <p>13 A. I don't agree with that --</p> <p>14 Q. (By Mr. De La Cerda) Why not?</p> <p>15 A. -- last statement. Because I'm not -- I'm</p> <p>16 disagreeing on the basis that there's -- they could</p> <p>17 not continue without doing the 5- -- the 522s. I</p> <p>18 think that a fair trial of this would have been to at</p> <p>19 least be on the committee that the FDA had. And there</p> <p>20 was actually the voice of surgeons saying these are --</p> <p>21 this is the evidence and part of the evidence was</p> <p>22 presented on a communication. It was signed by over</p> <p>23 400 surgeons and still that was ignored.</p> <p>24 And that has less to do with what Ethicon</p>
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<p>1 Q. And then Gynemesh, the indication was</p> <p>2 changed from -- well, I guess before there were two</p> <p>3 indications, then they changed it to just one. So now</p> <p>4 the indication for transvaginal implant was removed</p> <p>5 and now it's just abdominal sacrocolpopexy; is that</p> <p>6 right?</p> <p>7 A. That's correct.</p> <p>8 MR. SNELL: I'm going to object. Wait.</p> <p>9 Wait.</p> <p>10 THE WITNESS: Okay.</p> <p>11 MR. SNELL: Objection, foundation, misstates</p> <p>12 the evidence and the clearance.</p> <p>13 So go ahead.</p> <p>14 Q. (By Mr. De La Cerda) So that's -- is that</p> <p>15 your understanding of what was done is that Prolift</p> <p>16 and Prosima were pulled from the market but Gynemesh</p> <p>17 wasn't, just its indication was changed?</p> <p>18 MR. SNELL: I'm going to have to object. I</p> <p>19 didn't hear "pulled from the market." Same</p> <p>20 objection, misstates the evidence.</p> <p>21 If you take my basis, I'm sure you can get a</p> <p>22 clean question and answer.</p> <p>23 Q. (By Mr. De La Cerda) What I'll do is I'll</p> <p>24 ask it this way: When Ethicon invented a word</p>	<p>1 could do, the way I look at it, the way I appreciate</p> <p>2 it, and more to the fact that the FDA decided no, this</p> <p>3 is the way it's going to be, 522s or -- or not. So</p> <p>4 what could they do?</p> <p>5 Q. This is an interesting point that's come up</p> <p>6 in my mind. Why is it that the physicians didn't</p> <p>7 petition Ethicon to comply with the 522 orders? If</p> <p>8 the product was so good, why don't the physicians say,</p> <p>9 "Hey, Ethicon, this stuff is great, do the 522 orders,</p> <p>10 we know it's going to turn out great, we all win"?</p> <p>11 Why was there no petition for Ethicon to do</p> <p>12 that?</p> <p>13 MR. SNELL: Calls for speculation.</p> <p>14 A. I -- I don't know. That's exactly -- I'm</p> <p>15 going to -- I'm going to probably answer it that way</p> <p>16 because it calls for speculation.</p> <p>17 Q. (By Mr. De La Cerda) Ultimately, if the</p> <p>18 product's great, why didn't Ethicon do the studies?</p> <p>19 Have you ever been provided a rationale as</p> <p>20 to why Ethicon decided not to do the 522 studies?</p> <p>21 A. No, there was no -- no rationale and we</p> <p>22 still cannot find a rationale for that, for not</p> <p>23 complying with the 522. I think that you can -- you</p> <p>24 cannot tell a company how they're going to go about</p>

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<p>1 their -- running their business. Although I would 2 like, yeah, to have that power to tell everyone to run 3 their business, it's not like I'm going to be listened 4 on that. And there are other considerations that they 5 may have.</p> <p>6 I can tell you that from a surgeons' 7 perspective, yeah, we could have been compelled -- 8 going along the statement that you just made, we could 9 have been compelled to go to Ethicon and I think that 10 that was conveyed at some point, but there's no -- no 11 way to go about it when you're imposed a 522 just off 12 like that.</p> <p>13 And I think that part of it -- just to 14 elab- -- elaborate on that -- part of it was that we 15 saw -- we signed that petition, we signed that letter, 16 we say, "Please reconsider this. Let's find another 17 method to do this. There has to be a better method to 18 do this." And I think ten years from now we're going 19 to look back on this and we're going to say that was 20 an inadequate method. It was too rigid and we have to 21 find other methods to have these devices available to 22 surgeons.</p> <p>23 Q. Is it necessarily a bad thing, though, for 24 clinical studies to be required before another</p>	<p>1 it.</p> <p>2 Q. What do you mean by the "communication"? 3 Did Ethicon say, "Hey, take it off your shelves"? 4 A. No, we have a product manager in the 5 operating room and any of us that have -- any surgeon 6 that receives a letter would go and send it right away 7 to the product manager.</p> <p>8 Q. And what did the letter say? 9 A. That's the decommercialization letter. 10 Q. Okay. 11 A. And that was it. 12 Q. And so at the time it was decommercialized 13 did those products then get pulled from the shelves of 14 the hospital? 15 A. Yeah, that's it, they're in a separate cart 16 and the cart doesn't work anymore. I actually tried 17 to find one a few -- a few months later, I couldn't 18 find it. No, that goes to a facility, gets destroyed, 19 that's it.</p> <p>20 Q. Okay. Here's a few statements, I want to 21 see if you agree with them. 22 Do you agree serious complications 23 associated with surgical mesh for transvaginal repair 24 of pelvic organ prolapse are not rare?</p>
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<p>1 transvaginal pelvic organ prolapse mesh is put on the 2 market? I mean, is that a bad thing? Isn't that a 3 good thing because it can ensure safety for patients? 4 MR. SNELL: Form.</p> <p>5 A. I could -- let me tell you, I'm -- by now, 6 you know that I have done research in one way or 7 another for 25 years and I sponsor individuals to do 8 research and I believe in research and I believe in 9 evidence.</p> <p>10 I can -- I will never be able to say, "Oh, 11 no, we don't need another study." I think that 12 everybody wants another study, but the fact is that 13 are we going to put individuals through a study when 14 we have evidence from -- from before, multiple 15 randomized control trials, how fair is that to do 16 another study with women when we have evidence of how 17 it works?</p> <p>18 Q. (By Mr. De La Cerda) Do you know if any 19 of the hospitals that you have privileges at had any 20 Prolift or Prosima devices leftover after Ethicon 21 stopped selling those products? 22 A. No, that's -- in my -- my hospital, there 23 was -- it was not there. Basically the communication 24 came in and the communication is clear and that was</p>	<p>1 A. They are rare. 2 Q. They are rare? 3 A. They are rare. 4 Q. So you disagree with that statement? 5 A. I disagree with the statement that they are 6 not rare. 7 Q. Do you agree that there is no evidence that 8 transvaginal repair with mesh provides any added 9 benefit compared to traditional surgery without mesh? 10 A. That's inaccurate and it's not supported by 11 evidence. 12 Q. So you disagree with that one? 13 A. I do. 14 Q. Do you agree that it's not clear that 15 transvaginal repair with mesh is more effective than 16 traditional non-mesh repair in all patients with 17 pelvic organ prolapse and it may expose patients to 18 greater risk? Do you agree or disagree with that? 19 A. I disagree with that. 20 Q. Do you agree that mesh used in transvaginal 21 pelvic organ prolapse repair introduces risks not 22 present in traditional non-mesh surgery for pelvic 23 organ prolapse repair? 24 A. I -- in a general sense, I disagree with</p>

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<p>1 that except with a fact that the risk is inherent to 2 the implant only.</p> <p>3 Q. Which would be exposure; right?</p> <p>4 A. Which would be mesh exposure.</p> <p>5 Q. Mesh exposure. Mesh exposure.</p> <p>6 Okay. Do you agree mesh placed abdominally 7 for a pelvic organ prolapse repair results in lower 8 rates of mesh complications compared to transvaginal 9 pelvic organ prolapse surgery with mesh?</p> <p>10 A. I don't agree -- I don't agree with that. 11 And the basis for my disagreement with it isn't only 12 the clinical -- the clinical evidence, but also my 13 experience.</p> <p>14 Q. Do you agree that native tissue repairs have 15 similar outcomes to synthetic mesh without the risks 16 inherent in mesh use?</p> <p>17 MR. SNELL: Form, vague.</p> <p>18 A. They -- the evidence shows in randomized 19 control trials that native tissue repairs have 20 other -- other risks.</p> <p>21 Q. (By Mr. De La Cerda) So you would 22 disagree with this statement; right?</p> <p>23 A. Yes, I would.</p> <p>24 Q. Do you agree or disagree the native</p>	<p>1 correct?</p> <p>2 MR. SNELL: Same objection, speculation, 3 incomplete hypothetical.</p> <p>4 A. It's a -- it's reasonable on the basis of 5 human nature.</p> <p>6 Q. (By Mr. De La Cerda) At any point after 7 the July, 2011, FDA warning, did you decide to stop 8 using Prosima, Prolift or Gynemesh transvaginally?</p> <p>9 A. I think that everyone look at it and 10 everyone stop using it for the wrong reasons, less 11 because of evidence, and more because of the -- of the 12 fear of being involved in litigation, which is real, 13 and being involved in a situation having to explain 14 themselves when there is not a clear -- a clear 15 picture about the reality of it.</p> <p>16 Q. But you did stop using Prosima, Prolift and 17 Gynemesh transvaginally at some point after the July, 18 2011, FDA warning; right?</p> <p>19 A. I -- I think I continue using what -- what 20 it did, it did happen is that I communicated, "Listen, 21 we need to take a look at this," but I continued using 22 it.</p> <p>23 Q. You continued implanting it?</p> <p>24 A. Yes.</p>
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<p>1 tissue -- strike that.</p> <p>2 Do you believe it would be a reasonable 3 decision for a doctor to stop using the Prosima device 4 following the July, 2011, FDA warning?</p> <p>5 MR. SNELL: Incomplete hypothetical, 6 speculation.</p> <p>7 A. I think that there's a -- I mean, I will 8 have to think for all the other surgeons, but I think 9 it's reasonable whenever you have a letter from an 10 organization like the FDA and you -- all of us not 11 being completely -- completely aware of that process 12 on how it came through, it comes as a surprise that we 13 don't have a problem. I think it comes as a surprise 14 not only for us, it comes as a surprise for the 15 patients.</p> <p>16 Q. (By Mr. De La Cerda) So it would be 17 reasonable for a doctor to do that?</p> <p>18 A. I think it's reasonable for anyone to think 19 that there's something wrong and it requires a lot of 20 reading and a lot of research to really be in tune 21 with the reality.</p> <p>22 Q. And so it would also be reasonable for a 23 doctor to stop using the Prolift and the Gynemesh 24 transvaginally after that July, 2011, FDA warning;</p>	<p>1 Q. Until they were pulled from the market or 2 stopped, they were stopped selling or 3 decommercialized; right?</p> <p>4 A. Yes, once you have -- you have that, I 5 don't -- I don't want to use it.</p> <p>6 Q. Do you agree -- do you agree that surgical 7 mesh to repair pelvic organ prolapse is a high-risk 8 device?</p> <p>9 A. It's a --</p> <p>10 MR. SNELL: Foundation.</p> <p>11 Go ahead.</p> <p>12 A. It's a game like talking about 522, some 13 510(k)s, high risk, low risk, it's not -- it's not 14 scientifically accurate.</p> <p>15 I do agree that if you're going -- if you're 16 going to use it, you need to be well-trained on it, 17 and you just don't start doing prolapse or continence 18 procedures because a device is easy to use. You still 19 have to be trained and read what's behind all that. 20 That's my opinion of how I run my professional career. 21 It's my -- my profession.</p> <p>22 That's how we do it on credentialing in my 23 hospital, that's going to be up to the credentialing 24 institutions and the physicians to decide how much</p>

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<p>1 training they will -- they will have.</p> <p>2 Q. (By Mr. De La Cerda) And so at this</p> <p>3 point, you can't tell me whether you can label</p> <p>4 surgical mesh to repair pelvic organ prolapse as</p> <p>5 high risk; right?</p> <p>6 A. Yeah, it's labeled high risk and there's</p> <p>7 communication from the FDA labeling it high risk.</p> <p>8 What I -- I can tell you is that the terminology of</p> <p>9 high risk or low risk brings other implications. If</p> <p>10 you look at the evidence, I will say, "Well, you know,</p> <p>11 it's really a risky procedure like any surgery."</p> <p>12 Q. And so you're not going to offer testimony</p> <p>13 that the Gynemesh implanted transvaginally or the</p> <p>14 Prosima or Prolift are low-risk devices, are you?</p> <p>15 MR. SNELL: Objection, misstates his prior</p> <p>16 testimony.</p> <p>17 Go ahead.</p> <p>18 A. I will not go with low risk or high risk. I</p> <p>19 think that whole terminology is so -- is so</p> <p>20 nonspecific. What's -- if I -- if you compare it to a</p> <p>21 heart surgery, if you compare it to -- to any other --</p> <p>22 an appendectomy, there's always risk. So I cannot</p> <p>23 classify one way or the other.</p> <p>24 There's -- there's -- I believe that there</p>	<p>1 does not do better than a native tissue repair in</p> <p>2 terms of safety and efficacy, do you think it should</p> <p>3 be introduced to the market?</p> <p>4 MR. SNELL: Foundation.</p> <p>5 Go ahead.</p> <p>6 A. The -- the basis for Prosima for any other</p> <p>7 procedure, they don't do well with whatever benchmark</p> <p>8 that you use, you need to reconsider, you need -- you</p> <p>9 have a choice in the market, obviously, but there's --</p> <p>10 that's not what we saw with Prosima. The cohort</p> <p>11 studies done on Prosima follow the experience with</p> <p>12 Prolift and it showed that it was better than native</p> <p>13 tissue repairs.</p> <p>14 Q. (By Mr. De La Cerda) You're aware that</p> <p>15 Ethicon was told by some of its top consultants it</p> <p>16 did not make sense to use the Prosima in people with</p> <p>17 lesser degrees of prolapse given the outcomes?</p> <p>18 A. Any consultant may have an opinion. That's</p> <p>19 something that -- that's something that Ethicon always</p> <p>20 foster for anyone to give an opinion. And it's not</p> <p>21 like we were that shy of giving an opinion because we</p> <p>22 actually offer plenty of it.</p> <p>23 Q. Would you disagree with that -- this</p> <p>24 particular opinion?</p>
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<p>1 is more to that high-risk, low-risk classification</p> <p>2 than what we can actually explain on the frame of a</p> <p>3 deposition.</p> <p>4 Q. (By Mr. De La Cerda) Do you know whether</p> <p>5 or not Ethicon did an internal risks analysis to</p> <p>6 determine risk scores for the pelvic organ prolapse</p> <p>7 mesh devices? Like whether they were going to --</p> <p>8 whether Ethicon was going to label them low,</p> <p>9 moderate, high risk?</p> <p>10 A. I'm not aware of them doing that and</p> <p>11 actually, there's -- there was an effort, not by</p> <p>12 Ethicon but by the professional societies to use the</p> <p>13 Dindo classification and modify it for -- for</p> <p>14 prolapse. So that's -- that tells you the extent.</p> <p>15 The reason why I'm explaining is it tells</p> <p>16 you the extent of how elaborate the process is. I</p> <p>17 don't think that Ethicon probably -- I think they were</p> <p>18 too busy with other things to develop anything,</p> <p>19 anything like that.</p> <p>20 Q. Let's switch gears a little bit here.</p> <p>21 Are you okay on breaks?</p> <p>22 A. I'm good.</p> <p>23 Q. Okay. We are getting close. Okay.</p> <p>24 If a synthetic graft product like Prosima</p>	<p>1 A. I disagree.</p> <p>2 Q. Do you agree or disagree with the following</p> <p>3 statement: There is no authoritative paper to support</p> <p>4 that Prosima outcomes are superior or even comparable</p> <p>5 to colporrhaphy?</p> <p>6 A. I disagree with that, and the papers are</p> <p>7 authoritative and within the context of evidence</p> <p>8 previously gathered by the use of Gynemesh and</p> <p>9 Prolift.</p> <p>10 Q. So if the primary investigator for the</p> <p>11 Prosima trial which studied whether or not the product</p> <p>12 was effective for Grade II and III rectocele and</p> <p>13 cystoceles made that statement, you would disagree</p> <p>14 with her?</p> <p>15 A. I'm not aware -- are you speaking about</p> <p>16 Dr. Zyczynski?</p> <p>17 Q. I guess ultimately -- you know, what I'll</p> <p>18 do, I'll just withdraw the question. I think you've</p> <p>19 already answered anyway.</p> <p>20 You disagree with the prior statement, so I</p> <p>21 think you answered that anyway.</p> <p>22 A. I'm going to refer to her on first name</p> <p>23 because I think that she will be okay with it. Her</p> <p>24 first name is Halina, H-a-l-i-n-a.</p>

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<p>1 Q. If the overall consensus of a medical device 2 company's consultants and experts is that it would be 3 a mistake to launch a device on the market, do you 4 think it would be wrongful for the company to launch 5 that device anyway?</p> <p>6 A. The --</p> <p>7 MR. SNELL: Wait. Hold on. Objection, 8 speculation, incomplete hypothetical.</p> <p>9 A. The fact that you are a scientist doesn't 10 always mean that you're going to know marketing. 11 That's -- there's more than one person making those 12 decisions.</p> <p>13 Q. (By Mr. De La Cerda) So you don't believe 14 that it would necessarily be wrongful for a company 15 to launch a product under those circumstances; is 16 that right?</p> <p>17 MR. SNELL: Same objection.</p> <p>18 A. I think there's more than one opinion that 19 needs to be considered, especially in a multicenter 20 study.</p> <p>21 Q. If the overall consensus of a medical device 22 company's scientists and experts is that it would be a 23 mistake to launch the device on to a market, do you 24 think that doctors or patients who are provided the</p>	<p>1 MR. SNELL: Hold on. You've got to give me 2 a chance.</p> <p>3 Form, foundation.</p> <p>4 Go ahead.</p> <p>5 A. No, it's -- I don't think that's -- that 6 that should be considered. I think that the 7 scientific evidence supersedes whoever feels that it's 8 in so much power to say, "Oh, it's reckless because I 9 say it's reckless."</p> <p>10 Well, this is the evidence, this is the 11 scientific evidence, this is the multicenter evidence. 12 If you insist on calling it reckless or giving an 13 irresponsible opinion, which is what it is, then it's 14 up to you, but this is the evidence on this device.</p> <p>15 Q. (By Mr. De La Cerda) So Marcus Carey, you 16 know, is the inventor of Prosima; right?</p> <p>17 A. Yes.</p> <p>18 Q. And you know he received -- he would receive 19 royalties each time the Prosima was sold; right?</p> <p>20 MR. SNELL: Foundation.</p> <p>21 A. I -- I'm aware that he got paid for his 22 work.</p> <p>23 Q. (By Mr. De La Cerda) Do you know how much 24 he got paid?</p>
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<p>1 device should be told the company's scientists and 2 experts think that the device is a mistake?</p> <p>3 MR. SNELL: Form, foundation, incomplete 4 hypothetical.</p> <p>5 A. Yeah, I don't think that any company is 6 going to tell you, "Yeah, I'm going to release it and 7 it's mistake."</p> <p>8 No, the evidence is there and -- and the 9 evidence was so very clear with Prosima. It was 10 presented in modules, it was presented on the number 11 of patients, it was presented in a multicenter study. 12 It had all the qualities of a good cohort study.</p> <p>13 Q. (By Mr. De La Cerda) So you don't think 14 that a doctor or -- a doctor who's implanting a 15 Prosima or a patient who's going to receive a 16 Prosima wants to know before that Prosima is put in 17 that at some point the top consultants and experts 18 at the company believe that Prosima was a mistake, 19 they believe it was a reckless product, that they 20 believe if they put the product out on the market 21 they were going to stop working with Ethicon, you 22 don't think any of that information should be 23 provided to doctors or patients?</p> <p>24 A. No.</p>	<p>1 A. No.</p> <p>2 Q. Do you know he was the lead author on the 3 Prosima study done by Ethicon prior to launch?</p> <p>4 A. There was the first one and then there was 5 another study.</p> <p>6 Q. Do you know what his success rate was with 7 the Prosima in that first study?</p> <p>8 A. It's -- on the -- the first study was 9 around -- above the hymenal ring, I believe it was in 10 the '70s.</p> <p>11 Q. What about below? Below the -- I just lost 12 the word. Hymenian, is that what you said?</p> <p>13 A. Hymenal ring.</p> <p>14 Q. Hymenal ring.</p> <p>15 MR. SNELL: Let me caution you. If you have 16 a study, you should pull it out and look at it. 17 He's not asking you to guess. I mean, we have 18 all this stuff here, you can look at it.</p> <p>19 THE WITNESS: Okay.</p> <p>20 MR. SNELL: I don't know where you have it, 21 but I would assume it's in one of these things.</p> <p>22 A. This is it. This is the study.</p> <p>23 Q. (By Mr. De La Cerda) Okay. So go back to 24 the question. Do you know what his success rate was</p>

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<p>1 with the Prosima in his first study?</p> <p>2 A. Let me look through it and I'll --</p> <p>3 73.9 percent.</p> <p>4 Q. And you say that is above or below the</p> <p>5 hymenal ring?</p> <p>6 A. That's about the hymenal ring.</p> <p>7 Q. And how about below the hymenal ring?</p> <p>8 A. The rest of it.</p> <p>9 Q. What do you mean "the rest of it"?</p> <p>10 A. The other percentage.</p> <p>11 Q. So it's 70/30?</p> <p>12 A. Yes, it's 70 -- yes, it's 73.9 versus</p> <p>13 20-something. Either one, yeah.</p> <p>14 Q. Do you think the fact that he was the</p> <p>15 inventor of the product introduced bias in that study?</p> <p>16 THE WITNESS: Let me point out -- do you</p> <p>17 see -- you saw that, right?</p> <p>18 MR. SNELL: Okay.</p> <p>19 A. Please repeat the question.</p> <p>20 Q. Sure.</p> <p>21 Do you think the fact that he was the</p> <p>22 inventor of the Prosima introduced bias into that</p> <p>23 study?</p> <p>24 A. No.</p>	<p>1 Prolift?</p> <p>2 A. It was a group.</p> <p>3 Q. It was a group, right.</p> <p>4 A. It was a group.</p> <p>5 Q. You've relied on -- have you relied on data</p> <p>6 and literature published by Dr. Cosson and the TVM</p> <p>7 group to support your conclusions that Prolift is safe</p> <p>8 and effective?</p> <p>9 MR. SNELL: Same objection.</p> <p>10 A. Well, there was a TVM and there was Prolift.</p> <p>11 And TVM was a precursor, but is different from the</p> <p>12 product on Prolift.</p> <p>13 Q (By Mr. De La Cerda) Okay. Do you know if</p> <p>14 Dr. Cosson receives royalties for the Prolift or</p> <p>15 received?</p> <p>16 A. No, I don't -- I'm not aware of what he</p> <p>17 received.</p> <p>18 Q. Do you believe that an inventor who receives</p> <p>19 royalties for selling his invention can be potentially</p> <p>20 biased when publishing data regarding his invention?</p> <p>21 MR. SNELL: Speculation.</p> <p>22 A. I don't -- I don't see them being biased. I</p> <p>23 have no reason to believe that would be the case.</p> <p>24 Q. (By Mr. De La Cerda) You're very</p>
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<p>1 Q. Why not?</p> <p>2 A. I have no reason to believe that he would be</p> <p>3 bias with it.</p> <p>4 Q. Do you know whether Ethicon thought there</p> <p>5 was a fair amount of spin going on regarding Dr. Carey</p> <p>6 reporting of his clinical data?</p> <p>7 A. Fair amount of?</p> <p>8 Q. Spin. Have you ever heard that term "spin,"</p> <p>9 spinning the data, spinning the information?</p> <p>10 A. No, no.</p> <p>11 Q. Like the politicians do?</p> <p>12 A. I have no reason to believe that</p> <p>13 Professor Carey had any deviations from what he would</p> <p>14 honestly do.</p> <p>15 Q. Do you know whether Ethicon believed that</p> <p>16 Dr. Carey was spinning the data?</p> <p>17 A. No. No, I don't -- I'm not aware of that.</p> <p>18 Q. The inventor of Prolift, Dr. Cosson,</p> <p>19 C-o-s-s-o-n --</p> <p>20 A. Cosson.</p> <p>21 Q. Cosson.</p> <p>22 MR. SNELL: Misstates, lacks foundation.</p> <p>23 You've got the wrong person.</p> <p>24 Q (By Mr. De La Cerda) Is he the inventor of</p>	<p>1 trusting. You're very trusting.</p> <p>2 A. This is high caliber -- high-caliber</p> <p>3 investigators.</p> <p>4 Q. Well paid, too.</p> <p>5 You're aware that Ethicon had an alternative</p> <p>6 mesh to Gynemesh PS that they believe would cause</p> <p>7 fewer compli- -- fewer serious complications at least</p> <p>8 as early as 2006; right?</p> <p>9 MR. SNELL: Foundation, misstates the</p> <p>10 evidence.</p> <p>11 A. Could you please repeat that?</p> <p>12 Q. (By Mr. De La Cerda) Sure.</p> <p>13 Are you aware that Ethicon had an</p> <p>14 alternative mesh to Gynemesh PS that they believed</p> <p>15 would cause fewer complications at least as early as</p> <p>16 2006?</p> <p>17 MR. SNELL: Same objections.</p> <p>18 A. No, I'm not aware of that, any mesh like</p> <p>19 that, but I'm also aware that there's very low</p> <p>20 likelihood that there was any evidence strong enough</p> <p>21 for Prolene polypropylene.</p> <p>22 Q. (By Mr. De La Cerda) What do you mean by</p> <p>23 that?</p> <p>24 A. The evidence on Prolene polypropylene, on</p>

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<p>1 the behavior of the material, it's -- it was</p> <p>2 well-established by the time Gynemesh PS came in.</p> <p>3 Q. So you don't believe it's possible that</p> <p>4 Ethicon can have evidence that it had a mesh different</p> <p>5 from Gynemesh that they believe was safer than</p> <p>6 Gynemesh?</p> <p>7 MR. SNELL: Objection, same objection.</p> <p>8 A. I believe it's possible to have another</p> <p>9 mesh. What I don't believe is that the mesh could be</p> <p>10 based to be safer or with more evidence.</p> <p>11 Q. (By Mr. De La Cerda) Okay. I'm going to</p> <p>12 ask you whether you agree with the following</p> <p>13 statements.</p> <p>14 Do you agree that physicians should be</p> <p>15 aware -- made aware of all of the significant safety</p> <p>16 risks associated with the product in the IFU?</p> <p>17 MR. SNELL: Objection, asked and answered.</p> <p>18 I think he's testified three times on this.</p> <p>19 A. The -- the risk of the IFU should pertain to</p> <p>20 the device. There is no place in the IFU to make a</p> <p>21 more comprehensive guide for incontinence, nor should</p> <p>22 the IFU replace training, expertise and textbook</p> <p>23 reading.</p> <p>24 Q. (By Mr. De La Cerda) But you agree that</p>	<p>1 for it to exclude known hazards or complications?</p> <p>2 MR. SNELL: Form.</p> <p>3 Q. (By Mr. De La Cerda) There are</p> <p>4 circumstances where I think you believe that it can</p> <p>5 exclude known hazards and complications; right?</p> <p>6 MR. SNELL: Same objections.</p> <p>7 A. Things that are not at risk to the patient.</p> <p>8 Q. (By Mr. De La Cerda) No, I mean -- okay.</p> <p>9 If it's a known hazard or complication to it</p> <p>10 that could happen to a patient, should it ever be</p> <p>11 excluded from an IFU?</p> <p>12 MR. SNELL: Same objection.</p> <p>13 A. If it's -- if the complication or the side</p> <p>14 effect is the same as it would happen with a native</p> <p>15 tissue repair, I believe that it does not have to be</p> <p>16 included on the IFU.</p> <p>17 Q. (By Mr. De La Cerda) Okay. Do native</p> <p>18 tissue repairs result in chronic foreign body</p> <p>19 reaction?</p> <p>20 A. Yes.</p> <p>21 Q. How is that?</p> <p>22 A. There's a reaction to sutures. There's the</p> <p>23 plication of tissue that dehiscence. There is the</p> <p>24 formation of hematomas or granulomas. There are the</p>
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<p>1 all significant safety risks associated with the</p> <p>2 product should be included; right?</p> <p>3 MR. SNELL: Objection, misleads prior</p> <p>4 testimony.</p> <p>5 Go ahead.</p> <p>6 A. With the -- with the product specifically</p> <p>7 associated to the device and -- and -- and the mesh.</p> <p>8 Q. (By Mr. De La Cerda) Is that a "yes"?</p> <p>9 MR. SNELL: Objection, asked and answered.</p> <p>10 A. To the device and mesh, yes.</p> <p>11 Q. (By Mr. De La Cerda) Okay. Do you agree</p> <p>12 that a manufacturer of a medical device that would</p> <p>13 be implanted in a woman's body is required --</p> <p>14 actually, strike that.</p> <p>15 Do you agree that an IFU should never</p> <p>16 exclude known hazards or complications?</p> <p>17 MR. SNELL: Objection, I think this is all</p> <p>18 asked and answered. He's given the same opinions</p> <p>19 numerous times.</p> <p>20 Go ahead.</p> <p>21 A. The IFU should talk about the things that</p> <p>22 are inherent to the device. It's -- it's a guide</p> <p>23 about the device.</p> <p>24 Q. (By Mr. De La Cerda) Can't -- is it okay</p>	<p>1 inherent conditions of the host that could cause it,</p> <p>2 such as atrophy, autoimmune disorders, lichen planus.</p> <p>3 So there are a number of conditions that can make a</p> <p>4 native tissue repair not work, not work well or have</p> <p>5 granulation tissue or have chronic -- chronic</p> <p>6 inflammation.</p> <p>7 Q. Chronic inflammation. Okay.</p> <p>8 Do you agree that if a patient undergoes the</p> <p>9 TVT procedure under general anesthetic, it has the</p> <p>10 potential to put the patient at increased risk for</p> <p>11 urinary retention or urethral erosion?</p> <p>12 A. No.</p> <p>13 Q. And why is that?</p> <p>14 A. Initially, the idea was that when you put a</p> <p>15 midurethral sling, which is tension free, that you</p> <p>16 have to adjust it so the patient would not be on</p> <p>17 retention.</p> <p>18 It was -- it was later described that that</p> <p>19 may have been true for previous slings that were used</p> <p>20 ideally for vesical junction, but not for midurethral</p> <p>21 slings. Eventually, the data proved that to be</p> <p>22 correct, because the rate of voiding dysfunction was</p> <p>23 below 1 percent.</p> <p>24 So one of the -- one of the things that that</p>

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<p>1 experience validated is something that they didn't</p> <p>2 know, not even the inventor actually knew that, which</p> <p>3 is that there is some viscoelasticity to the implant</p> <p>4 itself.</p> <p>5 MR. DE LA CERDA: Okay. What I'd like to do</p> <p>6 now is take a break and review my notes and</p> <p>7 then --</p> <p>8 MR. SNELL: I'm ready for another bathroom</p> <p>9 break.</p> <p>10 MR. DE LA CERDA: We'll go off the record,</p> <p>11 thank you.</p> <p>12 (Thereupon, a recess was taken from</p> <p>13 3:24 p.m. until 3:45 p.m., after which the</p> <p>14 following proceedings were held:)</p> <p>15 Q. (By Mr. De La Cerda) Okay. Doctor, we're</p> <p>16 back on the record.</p> <p>17 There was one thing you mentioned that I</p> <p>18 wanted to make sure was clear. When we were talking</p> <p>19 about the compensation you had received as a</p> <p>20 consultant and then we had a discussion about trying</p> <p>21 to get --</p> <p>22 MR. SNELL: I haven't gotten that either.</p> <p>23 MR. DE LA CERDA: That's fine. That's fine.</p> <p>24 Get a better version.</p>	<p>1 Q. Okay. Okay. And then have you had a chance</p> <p>2 to review that on your own, that spreadsheet?</p> <p>3 A. I saw it before -- before the Cavness trial</p> <p>4 and I saw it at the Cavness trial.</p> <p>5 Q. And are you sure one way or the other</p> <p>6 whether those numbers are allocated versus real</p> <p>7 numbers?</p> <p>8 A. They're -- I know they're not real numbers</p> <p>9 because I would have -- I would have remembered that.</p> <p>10 Q. Yeah.</p> <p>11 A. The number is -- is high, and I don't</p> <p>12 remember having 1099s that were that high.</p> <p>13 Q. Okay. Okay. Have you understood all of my</p> <p>14 questions today?</p> <p>15 A. Yes, sir.</p> <p>16 Q. Have you answered them truthfully and to the</p> <p>17 best of your ability?</p> <p>18 A. Absolutely.</p> <p>19 Q. Is there any testimony that you would like</p> <p>20 to go back and change at this point?</p> <p>21 A. No.</p> <p>22 MR. DE LA CERDA: Okay. I'll pass the</p> <p>23 witness.</p> <p>24</p>
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<p>1 MR. SNELL: People are running around like</p> <p>2 on your side, too, like all over the place.</p> <p>3 Q. (By Mr. De La Cerda) There was a</p> <p>4 discussion about trying to get -- there's a</p> <p>5 spreadsheet that has listed out some of this</p> <p>6 information and you mentioned, "Well, it might only</p> <p>7 be money that was allocated for me, but not</p> <p>8 necessarily money that I made."</p> <p>9 Do you remember discussing that? You might</p> <p>10 not have used the term --</p> <p>11 A. Yes.</p> <p>12 Q. -- "allocated."</p> <p>13 A. Yes, they did their own allocations for what</p> <p>14 they were going to spend. It was a budget, internal</p> <p>15 thing from Ethicon, a budget planning. So it could --</p> <p>16 my point is that it could say a number -- it would</p> <p>17 never be higher than that number, but it was -- it</p> <p>18 could be lower than that.</p> <p>19 Q. So the numbers in the spreadsheet may just</p> <p>20 be what would have been an allocation or a budget for</p> <p>21 you for that year and it couldn't be higher, but it</p> <p>22 might be lower?</p> <p>23 A. But it might be lower, yes. It cannot be</p> <p>24 over that number.</p>	<p>1 CROSS-EXAMINATION</p> <p>2 BY MR. SNELL:</p> <p>3 Q. Doctor, I want to go through some topics and</p> <p>4 I'm actually going to go in the order that</p> <p>5 Mr. de la Cerda covered things just to make sure we're</p> <p>6 all clear on the record here about where you intend to</p> <p>7 testify and the bases and whatnot.</p> <p>8 Do you recall at the beginning of the</p> <p>9 deposition you were asked by Mr. de la Cerda about</p> <p>10 that Abbott study where some of the patients didn't</p> <p>11 return back to the implanting surgeon for care of a</p> <p>12 complication?</p> <p>13 A. Yes.</p> <p>14 Q. All right. In formulating your opinions on</p> <p>15 the devices we've been discussing today, are there</p> <p>16 studies in databases that have captive audiences that</p> <p>17 look at treatment over time regardless of whether it's</p> <p>18 the implanter, explanter, or someone else?</p> <p>19 A. No, there's -- one of the -- one of the</p> <p>20 things that we have with these type of procedures is</p> <p>21 that there have been tracks on Medicare databases,</p> <p>22 they -- and we have other -- other -- other databases</p> <p>23 that I -- and the citations I put, the Kaiser</p> <p>24 Permanente, that's --</p>

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<p>1 Q. Why don't we go there because that's what I</p> <p>2 was going to ask you about. If you turn to page 14</p> <p>3 and 15 --</p> <p>4 A. Yes, I got it.</p> <p>5 Q. -- of your TVT, TVT-O report. Do you</p> <p>6 identify different database studies that assess</p> <p>7 reoperation complication management regardless of who</p> <p>8 actually is doing that surgery?</p> <p>9 A. Right.</p> <p>10 Q. Okay.</p> <p>11 A. The Canadian registry, there is Medicare,</p> <p>12 and there's Kaiser Permanente.</p> <p>13 Q. So -- and did you find those studies to be</p> <p>14 reliable?</p> <p>15 A. That is -- that is reliable.</p> <p>16 Q. So let's take the first one that I'm looking</p> <p>17 at, it's reference No. 45 in your report, Jonsson</p> <p>18 Funk, J-o-n-s-s-o-n, Funk. It's the nine-year study</p> <p>19 where the rate of removal for mesh urethrolysis was</p> <p>20 3.7 percent.</p> <p>21 A. Yes.</p> <p>22 Q. Do you have a recollection as to whether</p> <p>23 that study contained, you know, over a 100,000</p> <p>24 patients or --</p>	<p>1 not respond to therapy, to treatment, or to the</p> <p>2 intervention.</p> <p>3 The second is that paper that you just</p> <p>4 mentioned, but the overwhelming data is so high in</p> <p>5 other areas, in other databases that we don't go by</p> <p>6 specific papers like that.</p> <p>7 Q. So the case series, can -- when you</p> <p>8 formulated your opinions, did you pay attention and</p> <p>9 put more effort -- more emphasis on higher level data?</p> <p>10 A. Not only formulate my opinions. In</p> <p>11 everything I read, I need -- I need to know what is it</p> <p>12 that I'm reading. And I put that scale, that bridge,</p> <p>13 some people see it as a pyramid, some people see it as</p> <p>14 a list. We know that case series are at the bottom,</p> <p>15 randomized control trials reviews are on the top.</p> <p>16 Q. The first study, the Jonsson Funk study, can</p> <p>17 you identify, just for the record, how many patients</p> <p>18 did that involve in the assessment?</p> <p>19 A. It's 188,454 eligible women.</p> <p>20 Q. And then the other footnotes, 46, 47, 48,</p> <p>21 and 49, were those also the different databases you</p> <p>22 mentioned?</p> <p>23 A. Right. The Canadian, the Canadian also has</p> <p>24 good reliability because the Canadian does have -- has</p>
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<p>1 A. There was -- I know for a fact it's over</p> <p>2 80,000 patients, close to -- close to 100,000</p> <p>3 patients. Most importantly, that rate of -- of</p> <p>4 revision was about 3 percent.</p> <p>5 Q. And did you see a similar rate as to about</p> <p>6 3 percent in different database studies and other</p> <p>7 studies like the Cochrane reviews and randomized</p> <p>8 control trials?</p> <p>9 A. Consistently you go from one paper to</p> <p>10 another to another and it's 3 percent. It's 2 percent</p> <p>11 on one, 3 percent. The maximum I have seen is</p> <p>12 5 percent. But the number that is most consistently</p> <p>13 repeated is 3 percent. And that's -- that's accurate</p> <p>14 to cite to the patients.</p> <p>15 Q. So in the Abbott study, let me ask you this.</p> <p>16 Do you recall that it was a case series based on</p> <p>17 tertiary referral centers by Dr. Karram, who I think</p> <p>18 plaintiff's counsel mentioned, and a couple other</p> <p>19 doctors?</p> <p>20 A. Yes, there are probably two papers that say</p> <p>21 patients would not follow through. The first one is</p> <p>22 about the -- a review about randomized control trials</p> <p>23 or any follow up in which patients do not show up,</p> <p>24 they tend to be considered as -- in the group that did</p>	<p>1 a tracking because of their socialized system. They</p> <p>2 have tracking. They are known to be able to track a</p> <p>3 variety of conditions, and this is just another one</p> <p>4 that they -- that they are -- they report.</p> <p>5 Q. And so I guess my question is: Did you find</p> <p>6 these database studies from different databases, based</p> <p>7 on the volume of patients assessed and the</p> <p>8 methodologies, to be more reliable than a case series</p> <p>9 in a limited number of patients?</p> <p>10 A. Absolutely, besides these are up in the</p> <p>11 hierarchy.</p> <p>12 Q. You were asked some questions about what you</p> <p>13 did in formulating your opinions and you've talked</p> <p>14 about and testified that you reviewed the medical</p> <p>15 literature. I want to make sure we're clear here.</p> <p>16 Did you also look at various Ethicon company</p> <p>17 documents and evaluate them?</p> <p>18 A. Yes, I -- I -- I did. I just -- in the</p> <p>19 order -- in the order that I read them, I -- I read</p> <p>20 them most remotely. In other words, I -- it has been</p> <p>21 more time since I read than from this.</p> <p>22 Q. Did you specifically identify in your report</p> <p>23 Ethicon documents on topics that Mr. de la Cerda asked</p> <p>24 you about, like mechanical cut versus laser cut, and</p>

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<p>1 degradation and pore size and things like that in your 2 reports?</p> <p>3 A. Well, by -- through the -- through my 4 testimony today, I address. There is no way I would 5 have been able to address it if I wouldn't have read 6 it.</p> <p>7 Q. I think you testified to this and you can 8 tell me if I'm correct or wrong.</p> <p>9 Did you earlier testify that based on all of 10 your analyses and the bases you talked about here 11 today, that you have not identified any 12 characteristics of the mesh that are a safety risk?</p> <p>13 A. Yeah, I don't -- I don't think that there 14 are concerns about safety on -- on -- on any of the 15 products that we were using. If I would have thought 16 there were concerns about safety to begin with, I 17 wouldn't have used them.</p> <p>18 Q. And besides the medical literature and the 19 high-level data that you have referenced, do you also 20 rely on your clinical experience?</p> <p>21 A. There's -- my experience is important, the 22 data is important, and the caliber of the data is 23 important. Not only that, my experience and the 24 experience of the people that I -- that I talk to.</p>	<p>1 education role, did you teach and cover the IFU with 2 other pelvic surgeons specific to these devices we 3 talked about today?</p> <p>4 A. We could -- we could make -- the answer is 5 yes. We could make any presentation and present any 6 slide, but at the end when we're working together in 7 the specimen and they collaborate, it's the IFU, the 8 one that comes out.</p> <p>9 And as a -- as a preceptor or as a teacher, 10 you need to know that IFU by -- by steps and know not 11 only what it says, but what it really says in terms of 12 mechanics. That's important for all -- all products.</p> <p>13 Q. And how many of the cadaver labs or these 14 labs that you did included covering the IFU with the 15 surgeons?</p> <p>16 A. Every single -- every single lab.</p> <p>17 Q. How many cadaver labs did you do on these 18 products? Your best estimate is fine.</p> <p>19 A. The VCS here did about six cadaver labs 20 locally. We had -- we used to go to Orlando and it 21 was very convenient for me because when I would miss 22 the plane, because I was seeing patients, I would just 23 drive up there, and it's -- and it was six in the max 24 year, maybe eight.</p>
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<p>1 You see, it's -- in medicine, we still -- we 2 still value very much the experience, the experience 3 of our colleagues, so I use that and I use also the 4 experience of -- my own experience and the experience 5 of those that investigate. People -- people that are 6 extremely talented are looking at studies.</p> <p>7 Q. And at the end, though, in formulating your 8 opinions and coming to your final conclusions about 9 the safety and efficacy of Gynemesh PS, Prolift, TVT, 10 TVT-O, did you put more weight into the randomized 11 level on control trials than individual experience or 12 case series?</p> <p>13 A. Randomized control trial is what -- what we 14 wish we would have on everything. But once you have a 15 few randomized control trials, you can build up with 16 other -- with the other studies. You cannot just do 17 the reverse, you have to build up on the strongest 18 ones.</p> <p>19 Q. You were asked a lot of questions about your 20 opinions on IFUs and you told Mr. de la Cerda various 21 grounds and bases for your opinions and you talked 22 about how you had reviewed IFUs over many years and 23 numerous times.</p> <p>24 Let me ask you this. In your professional</p>	<p>1 Q. Would there be just one surgeon at this 2 event or would there be multiple?</p> <p>3 A. No, multiple surgeons. There was more than 4 one -- one preceptor.</p> <p>5 Q. Do you have an estimate as to the number of 6 pelvic floor surgeons you would have worked with and 7 trained and went through the IFU with?</p> <p>8 A. I never -- never saw more than four. And if 9 I will have two, that would be good. We -- we started 10 with the IFU. We would teach the device and after 11 that, one of the opportunities that we have in the 12 cadaver lab is that we could dissect and get an 13 in-depth view of what -- where the devices went by 14 using the IFU. So it was the ultimate test for an IFU 15 and the test is on performance of the procedure.</p> <p>16 Q. You were asked questions about TVT and these 17 products and you expressed the opinion that you don't 18 think that the devices rope, curl, degrade, et cetera.</p> <p>19 Did you -- so let me -- so with that 20 preface, did you look at the literature to see whether 21 any of the studies in the patients reported a 22 difference or a hypothesis as to a difference as to 23 laser cut versus mechanical cut mesh? Are there any 24 studies that describe it?</p>

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<p>1 A. There is not -- there are no actual studies 2 that define one way or the other.</p> <p>3 There is actually the well-designed 4 randomized control trials, like the TOMUS, which is 5 evaluating midurethral sling, transobturator and 6 retropubic. And what -- in that specific study, which 7 is an excellent study, it's one of the pillars of what 8 we do, it's -- we -- we found out there was no 9 description of one or the other; and I have the 10 impression that both were used and there was never any 11 difference on it.</p> <p>12 Q. For the mechanical versus laser cut, do you 13 cover that in-depth in your report on pages 23 through 14 25?</p> <p>15 A. Yes.</p> <p>16 Q. Do you have -- is there a TVT-Secur report 17 over there?</p> <p>18 A. Yeah.</p> <p>19 Q. Do you recall a study by the name -- maybe 20 the first author's name was Neuman that looked at 21 TVT-O versus TVT-Secur and it reported percentages of 22 complications for erosion and dyspareunia and there 23 was a difference seen on dyspareunia which the authors 24 reported may have been to -- may have been due to</p>	<p>1 you see a study that has good science, but then it 2 becomes an opinion at the end.</p> <p>3 Q. Do you recall Mr. De al Cerda asking you 4 about a hypothetical that if laser cut mesh was three 5 times stiffer or more stiffer than mechanical cut mesh 6 would it lead to more complications and he may have 7 even mentioned exposure. Do you recall?</p> <p>8 A. Yeah, I do recall.</p> <p>9 Q. My question to you is: So in that study by 10 Neuman, did the laser cut mesh have a significantly 11 different rate of erosion than the mechanical cut 12 mesh?</p> <p>13 A. There's -- the rate of erosions were -- was 14 lower on the Secur. It was zero versus a 1.4 on the 15 TVT-O.</p> <p>16 Q. Have you found any reliable, convincing 17 clinical study evidence that, in your mind, 18 establishes that there is a significant difference in 19 laser and mechanical cut mesh when implanted with the 20 TVT devices in women?</p> <p>21 A. There has been no study up to now and, 22 obviously, I'm giving you the opinion that I will 23 welcome any study that makes a difference between -- 24 between the two of them.</p>
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<p>1 laser cut mesh. Do you recollect that?</p> <p>2 A. That's Dr. Menahem Neuman's study. He's in 3 Israel and he study -- he studied TVT-Secur.</p> <p>4 Q. What page are you on?</p> <p>5 A. That's 44.</p> <p>6 Q. And was that the only study that you were -- 7 that you found in your investigation in the clinical 8 application of these products on women that suggested 9 there may be a difference between the two?</p> <p>10 A. There's a -- there's another -- another 11 study that Bianchi-Ferraro and on the -- both of them, 12 there are TVT-Os and TVT-Securs compared and there's 13 no difference on them. That's -- this is just -- this 14 is just illustrate that mechanical cut and laser cut, 15 unless you put it on extreme conditions, way beyond 16 the stressors that would be found on the pelvis, there 17 is no significant difference on the behavior.</p> <p>18 Q. Page 45 on the Neuman study, you wrote that 19 the authors theorized that the laser cut mesh was to 20 blame for higher dyspareunia, but there is no 21 scientific data confirming that.</p> <p>22 A. There is no scientific data and that is just 23 an opinion and that's -- that's what we -- we have to 24 define what's science, what's an opinion. Sometimes</p>	<p>1 The Cochrane database, actually, did not 2 define that. There is no other study that has defined 3 it.</p> <p>4 Q. Do you have an opinion as to whether the 5 weight, pore size, and width of the TVT mesh is proper 6 in that device for the treatment of stress urinary 7 incontinence?</p> <p>8 A. For which device specifically?</p> <p>9 Q. For the TVT, TVT-O devices, do you believe 10 that the mesh is the proper weight, pore size, and 11 width?</p> <p>12 A. Yes, and that's -- that's -- that's a mesh 13 that has the evidence behind it.</p> <p>14 Q. And when you say "the evidence," are you 15 talking about the various evidence that you put into 16 your reports?</p> <p>17 A. Yeah, we have come to the point, even the 18 communication from the FDA, most recent one, just -- 19 just speaks about the standard for continence care 20 being a midurethral sling.</p> <p>21 Q. You were asked a question by plaintiff's 22 counsel about the lighter weight mesh and larger pore 23 mesh.</p> <p>24 Has any lighter weight or larger pore mesh</p>

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<p>1 been studied as much or demonstrated to be as useful</p> <p>2 and safe as the mesh in TVT for the application of</p> <p>3 stress incontinence?</p> <p>4 A. For -- for stress incontinence specifically,</p> <p>5 there is no other mesh that has been tested to the</p> <p>6 extent -- actually, there's no other continence</p> <p>7 procedure material that have been tested to the extent</p> <p>8 of TVT.</p> <p>9 Q. And is that all different types of studies</p> <p>10 or just randomized control trials?</p> <p>11 A. There are all types of studies that -- but</p> <p>12 predominantly randomized control trials as -- and</p> <p>13 we're talking about devices for urinary incontinence.</p> <p>14 Q. You were asked a lot of questions about</p> <p>15 degradation. Do you believe that the available data</p> <p>16 shows that the Prolene mesh degrades?</p> <p>17 A. No.</p> <p>18 MR. DE LA CERDA: Form.</p> <p>19 Q. (By Mr. Snell) And did you review</p> <p>20 specifically studies referenced by plaintiff's</p> <p>21 counsel and others, you went and looked for like the</p> <p>22 Clavé paper, that purportedly raised this issue of</p> <p>23 degradation?</p> <p>24 A. That is one descriptive paper in which we --</p>	<p>1 demonstrate degradation?</p> <p>2 A. No, the samples -- the samples were poorly</p> <p>3 treated to the point that they -- they were not given</p> <p>4 a good for analysis.</p> <p>5 Classically, explant -- explanted tissue --</p> <p>6 I'm sorry, explanted graft is not a good -- it's not a</p> <p>7 good sample to begin with, much less when you put it</p> <p>8 through -- through spectroscopy, spectroscopy or</p> <p>9 chromatography and much less through thermal --</p> <p>10 thermal changes.</p> <p>11 Q. Were there -- in the Clavé paper, did you</p> <p>12 see that the authors acknowledged that there was no</p> <p>13 control group to compare?</p> <p>14 A. No, that's not a control -- control study.</p> <p>15 That's barely a descriptive study.</p> <p>16 Q. Did you find any of the data that purported</p> <p>17 to raise this issue of the hypothesis degradation to</p> <p>18 be reliable?</p> <p>19 A. No, I have not seen one yet that proves</p> <p>20 degradation with any definition that I've been given</p> <p>21 of degradation.</p> <p>22 Q. Mr. de la Cerda asked you about cytotoxicity</p> <p>23 and your report -- your report, I believe, covers that</p> <p>24 pretty much in-depth.</p>
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<p>1 we can actually look at 26 samples of low density.</p> <p>2 That's 26 samples out of close to over 2 million --</p> <p>3 between 2 million and 3 million slings that I don't</p> <p>4 think you can reliably give any opinion on that and</p> <p>5 actually, if it would degrade, I would expect it to</p> <p>6 perform worse, and that's not the evidence that we</p> <p>7 have.</p> <p>8 Q. Is there evidence, long-term data, that</p> <p>9 shows sustained durability and low complications in</p> <p>10 your view?</p> <p>11 A. Yes. There is data at five years, ten years</p> <p>12 and now I believe there is data bordering on the 15</p> <p>13 years.</p> <p>14 Q. And is that data, in your opinion,</p> <p>15 consistent or inconsistent with the degradation</p> <p>16 theory?</p> <p>17 A. No.</p> <p>18 Q. What's that?</p> <p>19 A. It's not consistent with the degradation</p> <p>20 theory. It's actually inconsistent.</p> <p>21 Q. In the Clavé study, did you see that besides</p> <p>22 the fact that a minority of the mesh is -- had this</p> <p>23 surface cracking on SEM, when they actually did the</p> <p>24 chemical analytical testing, did those tests</p>	<p>1 A. Yes.</p> <p>2 Q. And you talked with Mr. de la Cerda about</p> <p>3 the various Ethicon documents and testing you've</p> <p>4 reviewed and your opinion about the different types</p> <p>5 and what those studies show or don't show.</p> <p>6 A. Yes, I -- I reviewed the -- Ethicon actually</p> <p>7 ask a third-party lab to do it. It's a third-party</p> <p>8 lab in Germany and the reports are clear on all the</p> <p>9 assays.</p> <p>10 Q. And I think Mr. de la Cerda asked you to</p> <p>11 identify, you know, the bases for your opinion for</p> <p>12 your cytotoxicity opinions and you identified those</p> <p>13 documents in your analysis.</p> <p>14 Let me ask you this. Is the basis for your</p> <p>15 cytotoxicity opinions also your personal experience on</p> <p>16 assessing cytotoxicity issues?</p> <p>17 MR. DE LA CERDA: Leading.</p> <p>18 A. Yeah, well, I assess cytotoxicity with word</p> <p>19 in science starting to see cytotoxicity in -- in 1985,</p> <p>20 from 1985 to 1986, that's all I did in the lab. And</p> <p>21 it's -- I did that -- I actually presented it at a</p> <p>22 conference on -- on pharmaco -- on molecular</p> <p>23 pharmacology. And that's -- that's my experience with</p> <p>24 it.</p>

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<p>1 Q. (By Mr. Snell) So you have personal</p> <p>2 experience in cytotoxicity analyses?</p> <p>3 A. I have done bench -- I have done bench work</p> <p>4 on cytotoxicity.</p> <p>5 Q. Did you also evaluate the clinical</p> <p>6 literature on these devices to see whether they</p> <p>7 documented or raised a phenomenon that you would</p> <p>8 attribute to cytotoxicity?</p> <p>9 A. I went through all these documents and I</p> <p>10 read the results on each one of them and I -- I'm in a</p> <p>11 good position to see what -- what the assays show.</p> <p>12 Q. In your opinion, is the TVT mesh cytotoxic?</p> <p>13 A. No.</p> <p>14 Q. You were asked about clinical data that was</p> <p>15 available before TVT-O -- the TVT-O device was</p> <p>16 marketed. Do you recall just covering that topic with</p> <p>17 Mr. de la Cerda?</p> <p>18 A. Yes.</p> <p>19 Q. Was there data on -- clinical data, clinical</p> <p>20 studies on the TVT device before TVT-O went to market?</p> <p>21 A. There was clinical data, yes.</p> <p>22 Q. Is that data relevant, in your opinion, to</p> <p>23 TVT-O?</p> <p>24 A. Yes, it is.</p>	<p>1 A. No. And TVT has not been as to a sarcoma</p> <p>2 and there is actual -- actually a publication about</p> <p>3 it.</p> <p>4 Q. I think in your report at page 26 you go</p> <p>5 through some of the different epidemiologic studies</p> <p>6 with regard to the polypropylene slings and cancer and</p> <p>7 sarcoma.</p> <p>8 A. On the --</p> <p>9 Q. On the --</p> <p>10 A. Which one of the reports?</p> <p>11 Q. Probably be TVT, TVT-O report, page 26.</p> <p>12 A. Yes.</p> <p>13 Q. The top paragraph where you state: "The</p> <p>14 available data does not show any causal links between</p> <p>15 polypropylene and cancer," and then you have numerous</p> <p>16 footnote citations.</p> <p>17 A. Actually, the evidence is for lack of the</p> <p>18 carcinogenic.</p> <p>19 Q. And as part of Exhibit 11 there is a paper</p> <p>20 by the lead author Linder where there was over 2,000</p> <p>21 midurethral sling patients who were analyzed. I'll</p> <p>22 just hand it to you. We'll make sure we put it back</p> <p>23 into Exhibit 11.</p> <p>24 A. Yes.</p>
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<p>1 Q. Is it the same mesh?</p> <p>2 A. It's the same implant.</p> <p>3 Q. You were asked about the MSDS sheet that you</p> <p>4 looked at for the raw polypropylene and a statement in</p> <p>5 it to the effect that the raw polypropylene -- I don't</p> <p>6 remember the specific, but it had something to do with</p> <p>7 compatibility.</p> <p>8 My question to you is this: Is the TVT</p> <p>9 compatible with the female human body implanted --</p> <p>10 implantation in the pelvis for treatment of stress</p> <p>11 incontinence?</p> <p>12 A. It is biocompatible. It has been</p> <p>13 demonstrated that it's biocompatible and it has no</p> <p>14 similarity to raw polypropylene.</p> <p>15 Q. That was going to be my next question. Is</p> <p>16 raw polypropylene implanted in the TVT process -- TVT</p> <p>17 device?</p> <p>18 A. It's a -- it's a different thing. Totally</p> <p>19 different -- different type of material.</p> <p>20 Q. There was a discussion about sarcoma</p> <p>21 formation in rats when raw polypropylene was implanted</p> <p>22 in disk or powder form. Do you recall that?</p> <p>23 A. Yes.</p> <p>24 Q. Is TVT disk or powder form?</p>	<p>1 Q. Is that one of the studies that form the</p> <p>2 basis of your opinion that the data show</p> <p>3 noncarcinogenic --</p> <p>4 A. The rate of cancer in these patients was</p> <p>5 reported to be below baseline.</p> <p>6 Q. Have you seen any studies utilizing the</p> <p>7 Prolene polypropylene in any of these devices we</p> <p>8 discussed today that show a statistically significant</p> <p>9 elevated risk of sarcoma formation or cancer in women</p> <p>10 over and above the expected background rate?</p> <p>11 A. No.</p> <p>12 Q. And in that study by Linder you just</p> <p>13 mentioned, is it correct that 49 of the 50 patients</p> <p>14 had cancer already a baseline?</p> <p>15 A. Yeah, that's -- that's the only -- it's 2</p> <p>16 out of 2,474. That's what makes for .0- -- 08.</p> <p>17 That's extremely low. That's actually lower than the</p> <p>18 reported -- one of the cases was an ovarian cancer and</p> <p>19 that's lower than the reported rate of ovarian cancer.</p> <p>20 Q. Let me put that back in Exhibit 11. Make</p> <p>21 sure we don't lose that.</p> <p>22 You were asked questions by Mr. de la</p> <p>23 Cerda -- I'm going to circle back around to the</p> <p>24 lighter weight, larger pore mesh theory.</p>

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<p>1 Do you know whether actually the TVM group</p> <p>2 evaluated a larger pore, lighter weight mesh in the</p> <p>3 development of what became Prolift --</p> <p>4 MR. DE LA CERDA: Leading.</p> <p>5 Q. (By Mr. Snell) -- that was besides</p> <p>6 Gynemesh PS?</p> <p>7 A. They did. They did and it's in my Reliance</p> <p>8 List. Professor Jack Tanny evaluated the IFUs of</p> <p>9 different meshes with absorbable components and with</p> <p>10 large pore size. Their first conclusion and that's</p> <p>11 non- -- the first conclusion wasn't Dr. -- Professor</p> <p>12 Berrocal, B-e-r-r-o-c-a-l.</p> <p>13 Professor Berrocal's paper in which the</p> <p>14 statement was clear the TVM group decided that no</p> <p>15 absorbable meshes were going to be used. And when a</p> <p>16 combination was used without a partial absorbable</p> <p>17 partial polypropylene, they decided that the pore size</p> <p>18 being so large did not work.</p> <p>19 Q. Did you see whether or not the surgeons</p> <p>20 evaluating the different meshes also evaluated a mesh</p> <p>21 called Vipro?</p> <p>22 A. They did. That's exactly what they did.</p> <p>23 Q. Is that a large pore, lightweight mesh as</p> <p>24 well?</p>	<p>1 Did you see any clinical studies that you</p> <p>2 found to be reliable that showed that a larger pore or</p> <p>3 lighter weight mesh than Gynemesh PS was more</p> <p>4 effective or safer than Gynemesh PS in the Prolift,</p> <p>5 Prosima or Prolapse application?</p> <p>6 A. No, it was -- it remained on a hypothesis.</p> <p>7 It remained just as a hypothesis and just we -- we all</p> <p>8 consider at one point that when we we're talking, I'm</p> <p>9 talking again about the surgeons, the word preceptors</p> <p>10 and the other surgeons, which one is going to have the</p> <p>11 longest data behind it and it was polypropylene.</p> <p>12 Q. You mentioned earlier, told Mr. de la Cerda,</p> <p>13 based on your review of the most reliable data that</p> <p>14 actually the Gynemesh PS and Prolift had a lower risk</p> <p>15 of wound complications in native tissue. Do you</p> <p>16 recall that?</p> <p>17 A. Yes.</p> <p>18 Q. And I think you also testified that based on</p> <p>19 your analysis, there was a lower rate or risk of</p> <p>20 vaginal stenosis requiring surgery for the Gynemesh PS</p> <p>21 compared to native tissue and you mentioned the Carey</p> <p>22 study?</p> <p>23 A. That is correct. That's accurate.</p> <p>24 Q. Was that the same Carey study we were</p>
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<p>1 A. Yeah, it's a large -- large pore. You can</p> <p>2 get pores as high as 5-, 6,000 microns.</p> <p>3 Q. Did that mesh demonstrate better efficacy or</p> <p>4 tolerability than the Gynemesh PS?</p> <p>5 A. No, actually it was -- the performance was</p> <p>6 worse.</p> <p>7 Q. You've heard of the mesh Ultrapro,</p> <p>8 obviously. Mr. de la Cerda talked to you today about</p> <p>9 presentations concerning the potential benefits of</p> <p>10 lighter weight or larger pore meshes.</p> <p>11 A. Yes.</p> <p>12 Q. Does the Ultrapro mesh also have a risk of</p> <p>13 mesh exposure?</p> <p>14 A. We had -- when we say "we," as the surgeons</p> <p>15 doing these procedures, we expected that it was going</p> <p>16 to be less mesh exposure. We actually found that it</p> <p>17 was exactly the same.</p> <p>18 Q. And same thing for dyspareunia or pain?</p> <p>19 A. Yes.</p> <p>20 Q. In your Prolift report -- do you have that</p> <p>21 handy? Let's go to page 10 and 11.</p> <p>22 A. Yes.</p> <p>23 Q. Before we actually get to that, let me ask</p> <p>24 you this.</p>	<p>1 looking at earlier?</p> <p>2 A. Yes.</p> <p>3 Q. Do you know where that is? I want to ask</p> <p>4 you a question about it.</p> <p>5 A. That is in the --</p> <p>6 Q. My question is: Do you have it over there</p> <p>7 somewhere? I just want to ask you a question about</p> <p>8 it.</p> <p>9 Oh, here it is.</p> <p>10 A. It is the paper before the last one on the</p> <p>11 top to the left.</p> <p>12 Q. So page 1384, does that report and what you</p> <p>13 referenced in that randomized control trial that there</p> <p>14 was a higher rate of reoperation for vaginal stenosis</p> <p>15 in native tissue compared to the mesh?</p> <p>16 A. That's correct.</p> <p>17 Q. Do you remember Mr. de la Cerda asked you</p> <p>18 did Ethicon ever test the pliability of the mesh?</p> <p>19 A. Yes, I do recall that.</p> <p>20 Q. Now, pliability of the mesh, I think you</p> <p>21 told Mr. de la Cerda, that that could be related to</p> <p>22 stenosis or pain.</p> <p>23 A. Well, it's -- one thing is that the</p> <p>24 pliability and the other thing is about the</p>

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<p>1 contraction or shrinkage and what we were talking was</p> <p>2 along the lines of what mesh contraction or mesh can</p> <p>3 increase the pliability. Pliability of a tissue or</p> <p>4 the elasticity of the tissue has more to do with the</p> <p>5 tissue itself.</p> <p>6 Now, the question is, if the mesh could add</p> <p>7 to this and the answer is every clinical indication of</p> <p>8 shrinkage or -- or elasticity does not hold the test</p> <p>9 of clinical evaluation. If there would be a</p> <p>10 shrinkage, there would be an actual contraction. The</p> <p>11 vagina would be shorter. And there is no -- there's</p> <p>12 no study that demonstrates that the vagina is shorter</p> <p>13 on this -- on all patients that have been repaired</p> <p>14 with mesh.</p> <p>15 We have had instances in which the vagina is</p> <p>16 shorter with native tissue repair because there's no</p> <p>17 augmentation with the mesh. So -- and that</p> <p>18 communication is not just on my opinion, that's part</p> <p>19 of the communication that was sent to the FDA.</p> <p>20 Q. Are you talking about the paper that was</p> <p>21 endorsed by hundreds of pelvic surgeons?</p> <p>22 A. Yes.</p> <p>23 Q. At page 10 and 11 of your report you talk</p> <p>24 about the Cochrane review and then the randomized</p>	<p>1 Q. Is that a high-level of evidence, a</p> <p>2 systematic review metanalysis?</p> <p>3 A. That is at the highest level.</p> <p>4 Q. And is that what your opinions are based</p> <p>5 upon?</p> <p>6 A. Yes.</p> <p>7 Q. You were asked questions by Mr. de la Cerda</p> <p>8 about characterization of mesh as high risk or low</p> <p>9 risk, and I think you basically disagreed and said you</p> <p>10 prefer to kind of evaluate it on its own terms. Is</p> <p>11 that correct or not?</p> <p>12 A. I -- I saw the classification of low risk or</p> <p>13 high risk to be restrictive and the question is if</p> <p>14 this -- if this procedure is done with mesh have a</p> <p>15 higher risk over native tissue repairs.</p> <p>16 Q. Did he -- I'm sorry, go ahead.</p> <p>17 A. And the answer to that is every time we look</p> <p>18 at that randomized control trial, the answer to that</p> <p>19 is no.</p> <p>20 Q. So my question is this: Have you put in</p> <p>21 your report and will you be prepared to discuss at</p> <p>22 trial how Prolift, Prosima, Gynemesh PS comparing</p> <p>23 risk, whether it's less risky or higher risk than</p> <p>24 native tissue repair for things that we talked about</p>
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<p>1 control data do not show a statistically significant</p> <p>2 difference in de novo dyspareunia, de novo pelvic</p> <p>3 pain, vaginal pain, change in sexual function, or</p> <p>4 change in vaginal length or vaginal caliber.</p> <p>5 A. That's the latest Cochrane review, that's</p> <p>6 exactly what it demonstrates.</p> <p>7 Q. And did you also assess the randomized</p> <p>8 control trials to see if that was an accurate</p> <p>9 statement, specifically for Gynemesh PS and Prolift?</p> <p>10 A. Yeah, there's a -- there's an actual --</p> <p>11 there's a -- there are randomized control trials and</p> <p>12 there is the Lowman paper in which mesh is placed</p> <p>13 transabdominally, sacrospinously on fixations,</p> <p>14 uterosacral suspensions, anterior/posterior repairs,</p> <p>15 they were all evaluated for the incidence of</p> <p>16 dyspareunia.</p> <p>17 Q. You mention that the urine analysis was</p> <p>18 consistent with the findings by Dietz and Maher, who</p> <p>19 did a systematic review and found no difference in</p> <p>20 post-operative or de novo dyspareunia or change in</p> <p>21 sexual function. Do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. And that citation is number 24?</p> <p>24 A. 24.</p>	<p>1 today with Mr. de la Cerda like recurrence, wound</p> <p>2 complications, pain, change in vaginal shape, length,</p> <p>3 things like that?</p> <p>4 MR. DE LA CERDA: Form.</p> <p>5 A. Surgery has risk. Surgery has multiple</p> <p>6 risk. Surgery for prolapse has specialized risk that</p> <p>7 we face every single time that we work with mesh or</p> <p>8 without mesh. We haven't had a mesh now for a few</p> <p>9 years and patients still having the same kind of</p> <p>10 complications that they had with the exception of a</p> <p>11 mesh exposure because there's no mesh.</p> <p>12 Incisions still dehiscence the same way,</p> <p>13 incisions still separate, challenges of wound healing</p> <p>14 are still seen, granulation tissue is still seen, and</p> <p>15 actually what we're seeing now is a higher rate of</p> <p>16 hysterectomies with -- with shorter vaginas.</p> <p>17 Q. (By Mr. Snell) Do you plan to discuss at</p> <p>18 trial how the rates and risks with the Gynemesh PS,</p> <p>19 Prolift, Prosima compare to the rates and risks with</p> <p>20 native tissue?</p> <p>21 MR. DE LA CERDA: Form.</p> <p>22 A. Yes.</p> <p>23 Q. (By Mr. Snell) For example, in your</p> <p>24 report, you -- so for your Prolift report, page 9,</p>

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<p>1 you have -- you have multiple studies that show the</p> <p>2 efficacy of Prolift and Gynemesh PS compared to</p> <p>3 native tissue. Do you see that?</p> <p>4 A. Yes.</p> <p>5 Q. Do you plan to talk about the different</p> <p>6 rates and risks of recurrence for mesh-based repair,</p> <p>7 particularly I'm focused on Ethicon Gynemesh PS and</p> <p>8 Prolift, Prosima compared to native tissue.</p> <p>9 MR. DE LA CERDA: Form.</p> <p>10 A. Yes.</p> <p>11 Q. (By Mr. Snell) And do you plan to discuss</p> <p>12 rates of wound complications, sexual function and</p> <p>13 dyspareunia for Ethicon's meshes compared to native</p> <p>14 tissue?</p> <p>15 MR. DE LA CERDA: Form.</p> <p>16 A. Yes, I plan -- I plan to testify on those.</p> <p>17 Q. (By Mr. Snell) And have you evaluated and</p> <p>18 investigated those issues?</p> <p>19 A. I have thoroughly evaluated. I have -- I</p> <p>20 run randomized control trial after randomized control</p> <p>21 trial. I have highlighted the areas that I feel are</p> <p>22 most important and I have summarized them today on</p> <p>23 my -- on my testimony.</p> <p>24 Q. And have you also identified those --</p>	<p>1</p> <p>2 CERTIFICATE OF OATH</p> <p>3</p> <p>4 STATE OF FLORIDA)</p> <p>5 COUNTY OF BROWARD)</p> <p>6</p> <p>7 I, JODY L. WARREN, Registered Professional</p> <p>8 Reporter, Florida Professional Reporter, Notary</p> <p>9 Public in and for the State of Florida at Large,</p> <p>10 certify that the witness, JAIME SEPULVEDA, M.D.,</p> <p>11 personally appeared before me on 3/30/16 and was</p> <p>12 duly sworn by me.</p> <p>13 DATED this 11th day of April, 2016.</p> <p>14</p> <p>15</p> <p>16</p> <hr/> <p>17 JODY L. WARREN, RPR, FPR</p> <p>18 Notary Public, State of Florida at Large</p> <p>19 My Commission Expires 2/28/19</p> <p>20 My Commission No. FF 188650</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>
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<p>1 examples of those data in your reports, as well?</p> <p>2 A. I am -- I am ready to go on presented on the</p> <p>3 numbers.</p> <p>4 Q. Lastly, Mr. de la Cerda asked you about if</p> <p>5 you had any plans for further work in the formulation</p> <p>6 or analysis. Obviously, you're being deposed today</p> <p>7 and tomorrow and I will represent to you that there</p> <p>8 are transcripts not yet available for plaintiffs'</p> <p>9 experts and some of plaintiffs' experts are not being</p> <p>10 deposed until even after you.</p> <p>11 Do you plan to review those transcripts when</p> <p>12 they're provided to you and assess them?</p> <p>13 A. I will -- I will evaluate them. I'll assess</p> <p>14 them, and I'm looking forward to see the scientific</p> <p>15 validity of it.</p> <p>16 MR. SNELL: Okay. That's all I have.</p> <p>17 MR. DE LA CERDA: Nothing further from me.</p> <p>18 MR. SNELL: Thank you.</p> <p>19 THE COURT REPORTER: Do either of you need a</p> <p>20 rough draft on this?</p> <p>21 MR. SPARKS: Yeah, I put my email on --</p> <p>22 MR. DE LA CERDA: Yeah, I'll take one, too.</p> <p>23 (Thereupon, the taking of the deposition</p> <p>24 was concluded at 4:33 p.m.)</p>	<p>1 CERTIFICATE OF REPORTER</p> <p>2</p> <p>3 I, JODY L. WARREN, Registered Professional</p> <p>4 Reporter, Florida Professional Reporter, certify</p> <p>5 that I was authorized to and did stenographically</p> <p>6 report the deposition of JAIME SEPULVEDA, M.D., the</p> <p>7 witness herein on 3/30/16; that a review of the</p> <p>8 transcript was requested; that the foregoing pages</p> <p>9 are a true and complete record of my stenographic</p> <p>10 notes of the deposition by said witness.</p> <p>11 I further certify that I am not a relative,</p> <p>12 employee, attorney, or counsel of any of the</p> <p>13 parties, nor am I a relative or employee of any of</p> <p>14 the parties' attorney or counsel connected with the</p> <p>15 action, nor am I financially interested in the</p> <p>16 action.</p> <p>17 DATED this 11th day of April, 2016.</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <hr/> <p>22 JODY L. WARREN, RPR, FPR</p> <p>23 Notary Public, State of Florida at Large</p> <p>24</p>

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Page 302		Page 304	
1	- - - - -	1	LAWYER'S NOTES
2	E R R A T A	2	PAGE LINE
3	- - - - -	3	_____
4	PAGE LINE CHANGE	4	_____
5	_____	5	_____
6	REASON: _____	6	_____
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21	_____	21	_____
22	REASON: _____	22	_____
23	_____	23	_____
24	REASON: _____	24	_____

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1	
2	ACKNOWLEDGMENT OF DEPONENT
3	
4	I, _____, do
5	hereby certify that I have read the
6	foregoing pages, and that the same is
7	a correct transcription of the answers
8	given by me to the questions therein
9	propounded, except for the corrections or
10	changes in form or substance, if any,
11	noted in the attached Errata Sheet.
12	
13	
14	_____
15	JAIME SEPULVEDA, M.D. DATE
16	
17	
18	Subscribed and sworn
19	to before me this
20	_____ day of _____, 20____.
21	My commission expires: _____
22	_____
23	Notary Public
24	

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Exhibit E

Jaime Sepulveda

Reliance List ***in Addition to Materials Referenced in Report***

MDL Wave 3

Medical Literature

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Document Description [Bates Range]
(Milani) Ethicon 3 Year Study Prolift+M
08/25/2011 Correspondence from Public Citizen to Margaret A. Hamburg, M.D., Jeffrey E. Shuren, M.D., and Division of Dockets Management
2006 (Rezapour) A 3-Month preclinical trial to assess the performance of a new TVT-like mesh (TVTx) in a sheep model
2006 Mar 3 Flatow memo - CPC-2006-0165 Performance evaluation of TVT PROLENE blue Mesh_ Elongation Properties of Mechanical Cut verses Laser Cut
2011 Native Pelvic Organ Prolapse Patient Counseling Guide
2015.01.30 Blankenship forwarding Margolis (IME) Documentation
24 Hour Summary of the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee Meeting [02.26.2016].
A Solution-Gynecare TVT Tension-Free Support for Incontinence.
Application FEMA for TVT Secur
August 10, 2007 Email from Jiyoung Dang to Lisa Bryan regarding K071512 S01
Australian Pelvic Floor Discussion
Barber, M.D., et al. "Defining Success After Surgery for Pelvic Organ Prolapse." Obstet Gynecol (2009) 114:600-609.
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Brigitte Fatton Powerpoint Presentation entitled "Complications in Pelvic Floor Dysfunction Surgery: evaluation and management.
Classification Website Intro "An International Urogynecological Association (IUGA/International Continence Society (ICS) Joint Terminology and Classification of the Complications Related Directly to the Insertionm of Prostheses (Meshes, Implants, Tapes) & Grafts in Female Pelvic Floor Surgery."
Clinical Evaluation Report - Gynecare Prolift signed by P. Hinoul on 04.26.2013
Correspondence between Morgan Liscinsky of FDA & Bloomberg re: Johnson & Johnson Vaginal Mesh Implant.
Dear Surgeon Letter from Piet Hinoul and Aaron Kirkemo.
Dear Surgeon Letter, from Hinoul/ Henderson, re: Ethicon Gynecare U.S. Commercialization Decision, Customer Letter, 5/15/2012
Declaration of Reynaldo Librojo in Support of Motion for Summary
DEPO.ETH.MESH.00004755 - Guidoin Explant
Document entitled "Delay in Prosima Activities"
Document entitled "Pelvic Floor Repair. Extended Review of Medical Literature."
DX23600-R.1-3 - Prolene Resin Manufacturing Specifications 1.23.03
Email from Seppa re: Performance Evaluation of TVT Secur PROLENE Mesh: Mechanical vs. Laser Cut. Study (LIMS #BE-2004-1920)
Email from Seppa re: Performance Evaluation of TVT U PROLENE Mesh: Mechanical vs. Laser Cut. Study (LIMS #BE-2004-1920) Version 2
Email string re - Revised write up of the DeLeval and Waltregny visit
Email string re: Ultrapro vs Prolene Soft Mesh
Email string, top one from Gary Pruden to David Robinson, et al. re: article entitled :Vaginal repair with mesh no better than colporrhapy for pelvic organ prolapse.

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EQUH Brand Equity Study, Final Report, 01/2010
ETH.MESH.00082651-54
ETH.MESH.07903682-83
ETH.MESH.09268043-45
ETH.10285 - Prolift IFU (2005)
ETH.10977 - Prolift IFU (2009)
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ETH.MESH.00001595-1606 - Reisenauer, C. Anatomical conditions for pelvic floor reconstruction with polypropylene implant and its application for the treatment of vaginal prolapse. European Journal of Obstetrics & Gynecology and Reproductive Biology 2006
ETH.MESH.00003895 - Continence Health and Pelvic Floor Advisory Board Opening Comments for Renee
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ETH.MESH.00018382 - Powerpoint GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh in the Treatment of Pelvic Organ Prolapse
ETH.MESH.00018382 - Powerpoint GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh in Treatment of POP
ETH.MESH.00018382 - Powerpoint: Gynecare Gynemesh PS Nonabsorbable Prolene Soft Mesh in the Treatment of Pelvic Organ Prolapse
ETH.MESH.00019117 to ETH.MESH.00019121 Letter from Scott H. Jones to Price St. Hilaire re: Prosima US Launch Plan; cc: Renee Selman, et al.
ETH.MESH.00031323 - February 8, 2005 Memo to Customer from Sean M. O'Bryan regarding Gynecare Prolift* Pelvic Floor Repair System
ETH.MESH.00031324-25 - Letter to Gregory Jones from Celia M. Witten with FDA dated 1.8.02 regarding K013718 Trade name Gynemesh Prolene Soft Nonabsorbable Synthetic Surgical Mesh for Pelvic Floor Repair
ETH.MESH.00033400 - Patient Brochure: One Day You Have Prolapse, the Next Day You Don't
ETH.MESH.00034061-069 - Gynecare TVT SECUR* System: Key Technical Points
ETH.MESH.00064002 to ETH.MESH.00064004 Email string, top one from Judith Gauld to Scott Jones re: US preceptors for Prosima.
ETH.MESH.00064054 to ETH.MESH.00064054 Gynecare Prosima™ Pelvic Floor Repair System - Global Launch Strategy
ETH.MESH.00064138 to ETH.MESH.00064139 Document entitled "PROSIMA Critical Success Factors."
ETH.MESH.00066817 - Draft for Review 10/15/08, Letter from Ethicon Medical Affairs (To be used to respond to Physician Inquiries about FDA notification)
ETH.MESH.00071755 to ETH.MESH.00071755 Prosima - Apical Support Learning Guide
ETH.MESH.00071794 - Email re: TVT IFUs on tape extrusion, exposure and erosion
ETH.MESH.00076167 to ETH.MESH.00076167 Letter from Bryan Lisa to Dan Smith re: Prosima Product Release Authorization; cc: Stephanie Kute, Jennifer Paine.

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ETH.MESH.00076710 to ETH.MESH.00076790 Clinical Study Report. Evaluation of Prosima for Pelvic Organ Prolapse. Protocol Number: 300-06-005. "A Prospective, Multi-centre Study to Evaluate the Clinical Performance of Gynecare Prosima Pelvic Floor Repair System as a Procedure for Pelvic Organ Prolapse."
ETH.MESH.00077073-093
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ETH.MESH.00078114 to ETH.MESH.00078115 Memo to Prosima Regulatory File. Minutes from Teleconference with FDA for Prosima 510(k).
ETH.MESH.00082651 to ETH.MESH.00082654 Email string, top one from Marcus Carey to J. Meek, D. Robinson, P. Hinoul, et al. re: Technical feedback on Prosima.
ETH.MESH.00083812-14
ETH.MESH.00086463 to ETH.MESH.00086465 E-mail from Piet Hinoul to Zeb Viana, et al. regarding TR: PROSIMA TAKE AWAY MESSAGES; cc: Bart Pattyson, et al.
ETH.MESH.00108120 to ETH.MESH.00108121 Email string, top one from Douglas Grier to Lissette Caro-Rosado, et al. re: Pelvic Floor Advisory Board; cc: Bart Pattyson.
ETH.MESH.0011879; ETH.MESH.00093830 - Ethicon Women's Health & Urology — Clinical Compendium — Sales Rep Positioning
ETH.MESH.00125373 to ETH.MESH.00125373 Email string, top one from Tom Eagan to Erin Haggerty re: Dr. Sepulveda.
ETH.MESH.00126755-757 - Email string, top one from M. Yale to J. Paine, et al. re: Draft FDA response on Prolift+M for input
ETH.MESH.00127103 to ETH.MESH.00127103 Email from Greg prine to Scott Jones, Jonathan Meek re: Prosima Road Show; cc: Lesley Fronio and Kevin Mahar.
ETH.MESH.00127125-26 - Email From Lewis to Mahar, et al. re: How did Dr. Grier's Prosima cases go?
ETH.MESH.00129102 Suggested Remarks - Incontinence and Pelvic Floor Summit What a Difference a Decade Makes
ETH.MESH.00131149 to ETH.MESH.00131151 Email string, top one from Stephanie Grupe to Kevin Mahar re: Prosima Global Launch Team.
ETH.MESH.00144449 - Letter from David Robinson re: decision to delay preceptor training activities for Prosima (not signed).
ETH.MESH.00147507-509 - Approved September 16, 2008 - Marketing Services
ETH.MESH.00159266-369 - Gynemesh PS, Prolene Soft Mesh in the treatment of POP - Pelvic Floor Surgery and Anatomic Dissection Lab
ETH.MESH.00163952-960 - Gynecare TVT SECUR* System: Key Technical Points
ETH.MESH.00167104 -10 - 2006 Apr 19 - Laser Cut Mesh for Gynecare TVT- CER Laser Cut Mesh
ETH.MESH.00220335-36 - 12.2.1999 Memo re: Biocompatibility Risk Assessment for Soft Prolene Mesh.
ETH.MESH.00262015-016 - Dan Smith Email Plaintiffs Exhibit 2067
ETH.MESH.00271215-216 - Email from J. Meek to multiple recipients e: Pre-Reading for Prolift+M: Internal Use Only. Not Copy Reviewed or For Distribution
ETH.MESH.00273967 - Email from Clifford Volpe to Scott Jones re: slides for Pelvic Floor Summit.; Powerpoint: R&D Perspective - The Journey from Prolift to Prolift +M.
ETH.MESH.00281482-84
ETH.MESH.00291934-00291935 - Draft for Review 10/15/08, Letter from Ethicon Medical Affairs (To be used to respond to Physician Inquiries about FDA notification)

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ETH.MESH.00303310 to ETH.MESH.00303313 Memo from Dan Lamont to Gynecare Prosima Risk Management Report (RMR-0000029) re: Pelvic Floor Product(s) Complaint Review for Gyneacre Prosima Risk Management.
ETH.MESH.00308094 - Gynecare TVT SECUR* System Tension-free Support for Incontinence
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ETH.MESH.00318930 to ETH.MESH.00318930 (Draft) Letter from David Robinson re: delay in preceptor training activities for Prosima.
ETH.MESH.00318934 to ETH.MESH.00318934 Document entitled " Delay in Prosima Activities."
ETH.MESH.00327060-063 - Email from David Robinson to Catherine Beath November 12, 2007 RE: Australia update and telephone call with Prof Frazer
ETH.MESH.00329001-002 - Agenda & Minutes; TVT-Secur PQI07-041 Quality Board November 16, 2007
ETH.MESH.00330962-964 - Email from Christiana Bielinski to Aran Maree February 26, 2008 RE: FW: Communication to Surgeons Regarding the Gynecare TVT Secure System No Protective Marking - SEC=UNCLASSIFIED]
ETH.MESH.00335084 to ETH.MESH.00335085 Email from Daniel Lamont to Sungyoon Rha, et al. re: Mint Functional Strategies.
ETH.MESH.00349226-237 - May 26, 2000 Ethicon Memo to P. Cecchini RE: Review of Biocompatibility Data on the Tension Free Vaginal Tape (TVT) System for Compliance to FDA G-95/ ISO 10993/ EN 30993
ETH.MESH.00349228 - Cytotoxicity Risk Assessment for the TVT (Ulmsten) Device
ETH.MESH.00365412-414 - June 14, 2007 Memo RE: ADDENDUM: Post - Launch Complaint Review for the PROLIFT* Pelvic Floor Repair System
ETH.MESH.00365960 - Gynecare TVT Secur System Procedural Pearls & Frequently Asked Questions
ETH.MESH.00369995 - Treatment of Stress Urinary Incontinence with the GYNECARE TVT* Family of Products
ETH.MESH.00369999 - Treatment of Stress Urinary Incontinence with GYNECARE TVT SECUR* System
ETH.MESH.00370315 - Prosima Training Deck 1
ETH.MESH.00370392 - GYNECARE TVT SECUR* System Early Surgical Experience
ETH.MESH.00370421 - Clinical Considerations of the FDA Public Health Notification on the Use of Surgical Mesh in Female SUI and Gynecare TVT Obturator
ETH.MESH.00372664-671 - Letter from B. Lisa to J. Dang re: K071512 S04. (02.21.2008)
ETH.MESH.00373310 - Gynecare TVT Tension-Free Support for Incontinence: General Profession Education Deck.
ETH.MESH.00393045-46 - TVT-O Procedural Steps
ETH.MESH.00395374-380 - Scientific Advisory Panel on Pelvic Floor Repair Preliminary Minutes Chicago, IL June 22, 2001
ETH.MESH.00403003-017 - Cadaver Protocol/Competition Report
ETH.MESH.00405513-14
ETH.MESH.00409158 - Letter from David Robinson re: decision to delay preceptor training activities for Prosima (signed).

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ETH.MESH.00418855 to ETH.MESH.00418856 Email string, top one from Andrew Meek to Jonathan Fernandez, et al. re: Prosima Preceptor Recommendation Form; cc: Kevin Frost, et al.
ETH.MESH.00424374 to ETH.MESH.00424375 Email string, top one from Jonathan Fernandez to Rhonda Peebles re: remaining 2010 labs; cc: Robert Zipfel.
ETH.MESH.00426441 to ETH.MESH.00426441 Email from Kevin Frost to Robert Zipfel, et al. re: Prosima 2-year slide deck; cc: Paul Parisi.
ETH.MESH.00442129 - PowerPoint Mechanical vs. "Machine"-cut Mesh, January 19, 2005 Prepared by: Allison London Brown & Gene Kammere
ETH.MESH.00455676 to ETH.MESH.00455677 Email from Allison London Brown to Ophelie Berthier, et al. re: Prosima Jan 2007 update; cc: Bob Roda, et al.
ETH.MESH.00461576 - 10.23.2006 letter to EWHU field sales force
ETH.MESH.00467320 to ETH.MESH.00467320 Email string, top one from Andrew Meek to Bart Pattysen, Paul Parisi re: November Lab.
ETH.MESH.00495796 to ETH.MESH.00495798 Email string, top one from Jennifer Paradise to Melissa Doyle, et al. re: Prof Ed through Tele-Mentoring; cc: Paul Parisi, et al.
ETH.MESH.00510562 to ETH.MESH.00510563 Email string, top one from Kevin Frost to DL-ETHUSSO EWHU DMs, et al. re: 1st Prosima Virtual Round Table Tomorrow; cc: Matt Henderson, et al.
ETH.MESH.00516424-427
ETH.MESH.00523617-618 - Summary of Gynecare TVT Secur* System Critical Steps
ETH.MESH.00523942 - Waltregny 2005 ICS Presentation
ETH.MESH.00523942 - Waltregny TVT-O Summit
ETH.MESH.00526473-74 - Allison Brown Email re-Laser-cut Mesh
ETH.MESH.00527118-121 - Email from Joy Hovespian to Dharini Amin August 28, 2007 RE: FW: Dr. Sepulveda's notes summary/PLEASE DO NOT DISTRIBUTE. JUST FOR INTERNAL REVIEW
ETH.MESH.00541187-190 - Email from Carolyn Brennan to Joseph Scavona September 11, 2009 RE: TVT Secur Inserter Heads Up
ETH.MESH.00541379-80 - Mesh Fraying for TVT Devices
ETH.MESH.00541708 to ETH.MESH.00541709 Document entitled "Notes from Competitive Ad Board."
ETH.MESH.00541873 to ETH.MESH.00541873 Chart listing Proposed Lab Scheduling for August 4th.
ETH.MESH.00541876 to ETH.MESH.00541878 Email string, top one from Bart Pattysen to David Robinson, et al. re: ICS/IUGA Cadaver Lab - Monday Aug 23.
ETH.MESH.00542347 to ETH.MESH.00542348 Calendar appointment re: Prosima and Advanced Prolift Preceptorship with Dr. Sepulveda and Drs. Antar, Jones and Schlafstein.; created by Robert Zipfel.
ETH.MESH.00542463 to ETH.MESH.00542463 Powerpoint: Gynecare Prosima™ Pelvic Floor Repair System: 2-Year Clinical Data
ETH.MESH.00547021 to ETH.MESH.00547021 Ethicon Women's Health & Urology "Welcome Letter" to the EWH&U Pelvic Floor Repair Advisory Board Meeting.
ETH.MESH.00547036 to ETH.MESH.00547037 Email string, top one from Bart Pattysen to Jaime Sepulveda, et al re: Prosima (&Elevate) Advisory Board - Jan 8th - Baltimore; cc: Piet Hinoul, et al.
ETH.MESH.00547500-501 - Email re: 69% Success
ETH.MESH.00572598 - TVT Secur: European Feedback Axel Arnaud M.D.
ETH.MESH.00573815 to ETH.MESH.00573815 Powerpoint: Two Year Clinical Outcomes after Prolapse Surgery with Non-Anchored Mesh & Vaginal Support Device (Gynecare Prosima* Pelvic Floor Repair System) June 2010.

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ETH.MESH.00575257 - Abbrevio laser cut vs. mechanically cut - notes from meeting with de leval - inappropriate
ETH.MESH.00575270-273 - Jean de Leval Email Re: DSCN3332.JPG May 30, 2009
ETH.MESH.00575580 to ETH.MESH.00575581 Email string, top one from Jonathan Meek to Piet Hinoul, Colin Urquhart and Judi Gauld re: Prosima anterior compartment result.
ETH.MESH.00575634 to ETH.MESH.00575635 ICS 2009 Abstract Form. "Surgery for Pelvic Organ Prolapse Using Mesh Implants and a Vaginal Support Device: Analysis of Anatomic, Functional and Performance Outcomes from an International, Multicentre Study."
ETH.MESH.00576725-726 - MAUDE Review; Overall TVT Powerpoint
ETH.MESH.00578081 to ETH.MESH.00578083 Email string, top one from Piet Hinoul to Paan Hermansson re: Prosima Post launch communication.
ETH.MESH.00578550 to ETH.MESH.00578550 (Draft) Sayer, T., et al. "Two Year Clinical Outcomes after Prolapse Surgery with Non-Anchored Mesh and Vaginal Support Device."
ETH.MESH.00579296 to ETH.MESH.00579296 Powerpoint: Anatomic and Functional Outcomes of 2 Pelvic Floor Repair Systems Studied in Moderate and Severe Prolapse Patients.
ETH.MESH.00580588-89 - Email string dated 3/25/2010, top one from Piet Hinoul to Paan Hermansson re: key message for Prosima launch
ETH.MESH.00580711-13 - Email re: Piet explains PS in Prosima
ETH.MESH.00584811-13 - Email string re-Ultrasonic Slitting of Prolene Mesh for TVT
ETH.MESH.00584846-847 - (05.10.2004) Email string, top one from Gene Kammerer to Mora Melican, et al. re: Mesh for TVM.
ETH.MESH.00590896-897 - Piet Hinoul Email 3.11.09
ETH.MESH.00591563-65 - Email re: Smelly VSDs
ETH.MESH.00592224 to ETH.MESH.00592229 E-mail chain from Jonathan Meek to otehrs in regards to Technical Feedback on Prosima
ETH.MESH.00592585-87 - Email re: No RCT for Prosima
ETH.MESH.00594266 - Email re: Overstating Success - Less Misleading
ETH.MESH.00594455 - Email re: Stop communicating over email
ETH.MESH.00594528 Email from Aaron Kirkemo to Piet Hinoul, David Robinson and Judi Gauld re: Prosima commercial claims of 92.3% above the hymen.
ETH.MESH.00595468 to ETH.MESH.00595470 Goldman, H., FitzGerald, M. "Opposing Views: Transvaginal Mesh for Cystocele Repair," J Urol (2010) 183:430-432.
ETH.MESH.00595889 to ETH.MESH.00595890 Email string, top one from Kevin Frost to Aaron Kirkemo re: Prosima presentation; cc: Tom Affeld.
ETH.MESH.00596558-560 - Email from Dan Smith to Aaron Kirkemo RE: FW: Scion PA commercial recommendation
ETH.MESH.00604183 to ETH.MESH.00604186 Email string, top one from Piet Hinoul to Judi Gauld and Colin Urquhart re: PISQ, and score when unable to have sex.
ETH.MESH.00631782 to ETH.MESH.00631784 FDA Letter re: K063562 Gynecare Prosima
ETH.MESH.00658177-198 - Surgeons Resource Monograph
ETH.MESH.00662233 - Email from Scott Jones to DL-Ethusso dated 12/15/2009 re: PAGS Leads
ETH.MESH.00679637 to ETH.MESH.00679640 Email string, top one from Zenobia Walji to Ron Naughton, et al. re: Prolene Soft Mesh '05 proposed pricing; cc: Kevin Maher, et al.
ETH.MESH.00687819-22 - Email string re-Laser cut mesh

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ETH.MESH.00746179-180 - Email from Harel Gadot to Evridiki Kakoliri September 14, 2006 RE: TVT SECUR Launch activities
ETH.MESH.00746181-182 - Hold for Release Until 9/05/06, 8 a.m. EST Ethicon Introduces New Device to Treat Stress Incontinence
ETH.MESH.00759327 to ETH.MESH.00759335 Document entitled "Experience what's new in incontinence and pelvic floor repair." 2010 ICS IUGA Executive Agenda
ETH.MESH.00800521 to ETH.MESH.00800522 Email string, top one from Kenneth Pagel to Melissa Doyle re: presentation access.
ETH.MESH.00806974 to ETH.MESH.00806975 Email from Lissette Caro-Rosado to Jaime Sepulveda, et al. re: Pelvic Floor Advisory Board; cc: Bart Pattyson, et al.
ETH.MESH.00807570 to ETH.MESH.00807570 Revised Chart listing Proposed Lab Schedule
ETH.MESH.00807772 to ETH.MESH.00807774 Email String, top one from Bart Pattyson to Hugo Ye re: ICS-IUGA - Cadaver Lab & Ask the Expert Update; cc: Ping Li, et al.
ETH.MESH.00807972 to ETH.MESH.00807973 Email string, top one from Bart Pattyson to Tommaso Santini, et al. re: US Surgeon; cc: Tom Affeld.
ETH.MESH.00808121 to ETH.MESH.00808122 Email from bart Pattyson to Jaime Sepulveda et al. re: Prosima (&Elevate) Advisory Board - Jan 8th - Baltimore; cc: Piet Hinoul.
ETH.MESH.00817181 - Email dated 1/22/2010 from Scott Jones to Kevin Frost and Tom Affeld re: Summit Agenda/Moderator; cc: Matt Henderson, et al.
ETH.MESH.00820634 to ETH.MESH.00820634 Invitation to participate in Gynecare Prosima Virtual Round Table
ETH.MESH.00823549 - Application FMEA for TVT Secur
ETH.MESH.00833948 to ETH.MESH.00833949 Email from David Robinson to Jessica Shen re: Prosima Study.
ETH.MESH.00834910 to ETH.MESH.00834911 Email string , top one from David Robinson to Price St. Hilaire, et al. re: Prosima Strategic Council; cc: Kevin Mahar.
ETH.MESH.00839918-19 - Email from David Robinson September 20, 2006 RE: TVTS Complaint up to 20 September 06.ppt
ETH.MESH.00840886 to ETH.MESH.00840887 Calendar appointment re: Updated: TVT Secur Preceptor Roundtable Forum; created by Dharini Amin.
ETH.MESH.00843043 Email from David Robinson to Jacqutin Bernard, Judith Gauld and Jonathan Meek re: cancellation of scheduled Prosima training.
ETH.MESH.00845669-670 - Ethicon Memo December 4, 2007 RE: PQI-07-043 TVT Secur release mechanism
ETH.MESH.00849014-ETH.MESH.00849017
ETH.MESH.00850335 to ETH.MESH.00850336 Email string, top one from David Robinson to Stephanie Kute, Patrice Napoda re: Prosima FDA Review and IFU; cc: Price St. Hilaire, Dan Smith.
ETH.MESH.00851319-21 - E-mail string dated 1/21/2010, top one from Piet Hinoul to Clifford Volpe and David Robinson re: dimensions of the PROSIMA implant
ETH.MESH.00851319-321 - Email string, top one from P. Hinoul to C. Volpe, et al. re: Prosima implant dimensions.
ETH.MESH.00856579-82 - E-mail string dated 11/3/2010 re: neo clinical trial. Piet Hinoul: "Each individual study does not contribute to the success of those products
ETH.MESH.00857821 - Top Ten Reason to pursue Gynecare TVT Obturator System
ETH.MESH.00858080-081 - Perry Trial - Plaintiff's Exhibit 2313
ETH.MESH.00858096-97 - Gynecare R&D Monthly Update - May
ETH.MESH.00858175-176 - Mulberry Weekly Meeting MINUTES for 6.3.03

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ETH.MESH.00858252-53 - 2004 Memo from London Brown to Dan Smith re Mechanical Cut vs. Laser Cut Mesh Rationale
ETH.MESH.00863391 - T-366 - Dan Smith email - particle loss
ETH.MESH.00870466 - Ethicon Expert Meeting-Meshes for Pelvic floor
ETH.MESH.00870466-476 - (06.02.2006) Ethicon Expert Meeting: Meshes for Pelvic Floor Repair.
ETH.MESH.00872132-136 - Email from Dan Smith to Mark Yale September 15, 2006 RE: Potential quality issue on TVT-S
ETH.MESH.00873965-966 - Email from Mark Yale to Gary Borkes December 18, 2009 RE: FW: TVT-S Complant Review
ETH.MESH.00874280 - Email from Mark Yale to Laurent Soulier September 21, 2006 RE: Potential quality issue on TVT-S
ETH.MESH.00874445 - TVT-SECUR Quality Board
ETH.MESH.00895089 to ETH.MESH.00895091 Email string, top one from Kevin Frost to Vincenza Zaddem re: Prosima in R&D Study.
ETH.MESH.00921692 to ETH.MESH.00921694 Email string, top one from Tom Affeld to Scott Jones, et al. re: NEO #2, 3, 4 Lab Nominations; cc: Vincenza Zaddem.
ETH.MESH.00922443-446 - Email string, top one from P. St. Hilaire to B. Lisa, et al. re: Bidirectional elasticity statement
ETH.MESH.00925065 to ETH.MESH.00925067 Email string, top one from Joshua Samon to Vincenza Zaddem re: Mint Value Proposition; cc: Duan Broughton.
ETH.MESH.00993273 - 2006 TVT-O Anatomic Considerations Clinical Update Special Considerations Complications Summit Presentation by Raders and Lucente
ETH.MESH.00993273 - TVT Obturator Anatomic Considerations Clinical Update: Special Considerations, Complications.
ETH.MESH.00997751 - Clinical Expert Report for Gynecare TVT SECUR System
ETH.MESH.01037447-455 - Charlotte D. Owens Clinical Report on TVT-S
ETH.MESH.01059148-152 - Gynecare TVT-Secur 2007 Product Complaints Involving Serious Injury
ETH.MESH.01075187-215 - July 2, 2010 Clinical Expert Report - Gynecare Prolift* Pelvic Floor Repair System
ETH.MESH.01128679-698 - Brochure - Procedural Steps Gynecare TVT SECUR™ System - The Support is Here
ETH.MESH.01130568 - Ethicon, Inc. Worldwide Complaint-Reporting Statement Gynecare TVT Secur™ System
ETH.MESH.01136239-40 Email string, top one from Lissette Caro-Rosado to Ad Board Members re: EWH&U Pelvic Floor Repair Ad Board 1-8-11; cc: Tom Affeld, et al.
ETH.MESH.01154031-37 - Clinical Expert Report - Gynemesh Prolene Soft
ETH.MESH.01189392-395 - Summary of sheep and human cadaver labs for development of the GYNECARE TVT SECUR* System
ETH.MESH.01189423-439 - Martin Weisberg; Dave Robinson Clinical Report on TVT-S 2.28.06
ETH.MESH.01193925-930; ETH.MESH.0100644-645 - TVT-Secur: "Hammock" position; Minutes regarding events with Dr. Folke Flarn and training
ETH.MESH.01198058 to ETH.MESH.01198058 (Draft) Zyczynski, H., et al. "One year clinical outcomes after prolapse surgery with non-anchored mesh and vaginal support device."
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ETH.MESH.01201973 to ETH.MESH.01201973 Propsed Lab Schedule (2nd Revision)
ETH.MESH.01202189 - Stale Kvitle Email regarding Mini Me follow up from our visit May 20, 2009
ETH.MESH.01202190-191 - David Waltregny Email Re: Mini Me follow up from our visit May 21, 2009

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ETH.MESH.01203957-97 - The future of surgical meshes-the industry's perspective
ETH.MESH.01219542-48 - Review of Surgeon Responses of VOC Questionnaire
ETH.MESH.01220135-45 - Email string re-New Standards for Urethral Slings
ETH.MESH.01228079-84 - Nilsson Podcast Transcript
ETH.MESH.01237077-79 - Email dated 9/3/2009 from Piet Hinoul to David Robinson, et al. re: Prosima Take Away Messages; cc: Peter Meier
ETH.MESH.01237077-79 - Email re: Piet explaining why no Ultrapro in Prosima
ETH.MESH.01238454-56 - Email string re-TVTO length
ETH.MESH.01244824 to ETH.MESH.01244826 Email string, top one from Aaron Kirkemo to Cyrus Guidry re: response letter to editor, Lewis Wall.
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ETH.MESH.01264260 - Prolift +M Piet Hinoul Pelvic Floor Meeting Nderland Utrecht, May 7, 2009
ETH.MESH.01274741-743 - Use of UltraPro Mesh for Pelvic Organ Prolapse (POP) Repair through a Vaginal Approach.
ETH.MESH.01279975-976 - Harel Gadot Email re Next step in SUI sling
ETH.MESH.01317508-613 - TVT Factbook DHF - Revised 05.14.2001
ETH.MESH.01320351-67 - Corporate Product Characterization Plan, TVT-Laser Cut Mesh. Dated 02/06/2006.
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ETH.MESH.0141137 to ETH.MESH.0141039 Document re: summary of changes in mesh implant from Project Mint to final production.
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ETH.MESH.01678340 to ETH.MESH.01678340 Email from Andrew Meek to Melissa Doyle et al. re: Approved Prosima Receptors.
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ETH.MESH.01708180 to ETH.MESH.01708180 Chart listing financial information re: preceptors.
ETH.MESH.01708190 to ETH.MESH.01708190 Chart listing financial information re: preceptors.
ETH.MESH.01730626 to ETH.MESH.01730629 Email string, top one from Dr. Antar to Bart Pattyson re: Prosima presentation.
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ETH.MESH.01736775-791 - Martin Weisberg; Dave Robinson Clinical Report on TVT-S 2.20.06
ETH.MESH.01752532-35 - Mesh design argumentation issues
ETH.MESH.01760362-363 - Email from Michael Woods to David Robinson December 21, 2007 RE: Trial
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ETH.MESH.01782114-115 - (05.03.2006) Email string, top one from David Robinson to Carolyn Brennan re: Suzette email discussing problems with Prolift.

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ETH.MESH.01803816 to ETH.MESH.01803818 Summary re: Project Mint
ETH.MESH.01808311-318 - Trip Report Michael Tracey
ETH.MESH.01809082-83 - Memo re: VOC on new laser cut TVT mesh
ETH.MESH.01813259; ETH.MESH.02180759-61 - Email string with attachment re-Jeans Ideas.
ETH.MESH.01813975-78 - Email string re-FDA Prep-Plaintiff's Exhibit 460
ETH.MESH.01815027-029 - Key Human Cadaver Lab Reports used in the development of TVT SECUR
ETH.MESH.01821586-87 Email from Allison London Brown to Ophelie Berthier, et al. re: Prosima November update; cc: Bob Roda, Dan Smith, et al.
ETH.MESH.01822361-363 - Dan Smith Email regarding TVT Secur October 18, 2006
ETH.MESH.01822361-62 - Dan Smith Email regarding TVT-Secur leading to less retention
ETH.MESH.01824316-317 - Email from Dan Smith to Eric Gautheir November 6, 2006 RE: FW: TVT-S Complaint review
ETH.MESH.01954198-203 - Gynecare Clinical Expert Report - Gynecare Prolift* Pelvic Floor Repair System
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ETH.MESH.02010349 to ETH.MESH.02010362 Prosima Clinical Expert Report signed by David Robinson
ETH.MESH.02017152-158 - (02.23.2007) Ethicon Expert Meeting: Meshes for Pelvic Floor Repair.
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ETH.MESH.02059150-151 - May 24, 2006 Memo RE: First Post - Launch Complaint Review for the PROLIFT* Pelvic Floor Repair System
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ETH.MESH.02211912 - Annex 11: Porosity test on finished product - pelvic floor mesh.
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ETH.MESH.02229013 - Email re: IFU errors
ETH.MESH.02229051 - Video: "Biomechanics"
ETH.MESH.02229054 - Video: "What to Expect"
ETH.MESH.02229055 - Video: "VSD Case Series 1"
ETH.MESH.02232685 - Marketing: "Your Proof: Her dance class."

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ETH.MESH.02232854-874 - Prolift+M - Advanced User Discussion
ETH.MESH.02233126-187 - Prolift+M Educational Module
ETH.MESH.02233410 to ETH.MESH.02233406 US Launch - Premarket Preparation (PMP)
ETH.MESH.02233417 to ETH.MESH.02233417 Prosima New Product Request Form
ETH.MESH.02233418 to ETH.MESH.02233438 Prosima - Surgical Technique
ETH.MESH.02233439 to ETH.MESH.02233451 A New Operation for Vaginal Prolapse Repair Using Mesh and a Vaginal support Device: 1 Year Anatomic and Functional Results of an International, Multicenter Study.
ETH.MESH.02233452 to ETH.MESH.02233467 Prosima - Background and Development History
ETH.MESH.02233539 to ETH.MESH.02233539 Prosima - New Product Request Form
ETH.MESH.02233540 to ETH.MESH.02233625 Prosima - 2009 Sales Training Program
ETH.MESH.02233605 to ETH.MESH.02233605 (B&W) Webinar Invite "The treatment of Symptomatic Moderate Pelvic Organ Prolapse."
ETH.MESH.02233640 to ETH.MESH.02233640 (B&W) Prosima - Module 4: 2-Year Clinical Data
ETH.MESH.02233651 to ETH.MESH.02233673 One year Clinical Outcomes Following Prolapse Surgery with Non-Anchored Mesh and a Vaginal Support Device. Results from the International Multicenter Gynecare Prosima™ Study.
ETH.MESH.02233674 to ETH.MESH.02233692 (Marketing) "What is Gynecare Prosima Pelvic Floor Repair System?"
ETH.MESH.02233699 to ETH.MESH.02233710 Prosima - An Interview with Dr. Marcus P. Carey.
ETH.MESH.02233713 to ETH.MESH.02233714 Objective Success Rate Learning Guide
ETH.MESH.02233726 to ETH.MESH.02233727 Prosima Product Page on Ethicon-360
ETH.MESH.02233728 to ETH.MESH.02233728 (native) Gynecare Prosima™ Key Procedural Steps
ETH.MESH.02233834 to ETH.MESH.02233834 (B&W) 2009 Sales Aid Guide
ETH.MESH.02233840 to ETH.MESH.02233841 MRI Flashcard "Prosimia - The first fixationless mesh system that maintains anatomical position."
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ETH.MESH.02233881 to ETH.MESH.02233888 Zyczynski, H.M. "One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device." Am J Obstet Gynecol (2010) 203.
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ETH.MESH.02233963 to ETH.MESH.02233963 Virtual Round Table Invitation
ETH.MESH.02233964 to ETH.MESH.02233964 (B&W) Prosima DVD
ETH.MESH.02234001 to ETH.MESH.02234002 (Marketing) The Gynecare Prosima™ Pelvic Floor Repair System Story
ETH.MESH.02234005 to ETH.MESH.02234171 Prosima Sales Training Program
ETH.MESH.02234173 to ETH.MESH.02234177 Prosima Messaging practice Coaching Check List
ETH.MESH.02237103-104 - Gynecare TVT™ Family of Products Tension-free Support for Incontinence.

Production Materials

ETH.MESH.02237107 to ETH.MESH.02237115 Introducing Gynecare Prosima for Ethicon Epiphany 247.
ETH.MESH.02248778 - Mechanical vs Machine Cut (Laser.Ultrasonic) Mesh Particle loss less than 2 percent for both
ETH.MESH.02270724 - (07.19.2003) Email string, top one from Michel Cosson to Scott Ciarrocca re: Gynemesh holding force in tissue.
ETH.MESH.02270766-767 - (11.21.2003) Email string, top one from Michel Cosson to Scott Ciarrocca re: D'Art, risk question.
ETH.MESH.02270857-858 - (07.16.2004) Email from Laura Angelini to multiple recipients re: D'Art - Conversation with Prof. Jacquetin.
ETH.MESH.02286052-053 - Email string, top one from S. O'Bryan to S. Ciarrocca re: Prolift IFU
ETH.MESH.02318553 to ETH.MESH.02318554 Gynecare Prosima™ Combined Pelvic Floor Repair System Clinical Strategy.
ETH.MESH.02319312 - Memo re-TVT-base & TVT-O Complaint Review for Laser Cut Mesh Risk Analysis
ETH.MESH.02322037 to ETH.MESH.02322039 Email string, top one from Piet Hinoul to Aaron Kirkemo, et al. re: Neo clinical trial.
ETH.MESH.02330776 - GYNECARE TVT-Obturator System - The reporducible vaginal approach delivering results, precision and proven mesh
ETH.MESH.02340331-335 - TVT IFU (12.22.03 to 02.11.05)
ETH.MESH.02340568-591 - TVT Secur IFU
ETH.MESH.02340568-90 - TVT-S IFU
ETH.MESH.02340829-835 - TVT-O IFU - (01.07.04 to 03.04.05)
ETH.MESH.02341203-13 - TVT Abbrevo IFU
ETH.MESH.02341398-410 - Prosima IFU (6.18.10 to discontinuance) - English only 13 pages
ETH.MESH.02341398-453 - Prosima IFU
ETH.MESH.02341454-459 - Gynecare Prolift IFU (English Only)
ETH.MESH.02341522-527 - Gynecare Prolift IFU (English Only)
ETH.MESH.02341658-664 - Gynecare Prolift IFU (English Only)
ETH.MESH.02342194-196 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02342218-220 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02342250-252 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02342278-279 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02579701-06 - Email re: Piet re Problem with posterior inserter
ETH.MESH.02596085 - Letters to the Editor 2010; 1457
ETH.MESH.02596702 - TVT-Secur Workshop Dr. Sepulveda MC Erasmus Rotterdam 27/5
ETH.MESH.02596703-704 - TVT-Secur Workshop Dr. Sepulveda 27/5 Procedural Guidelines for Hammock placement
ETH.MESH.02597949 to ETH.MESH.02597950 Hinoul, P., et al. "A "mesh" made in heaven: synergy between the urogynaecological device industry and evidence based medicine."
ETH.MESH.02599918 to ETH.MESH.02599920 Email string, top one from Piet Hinoul to Kevin Frost re: 1-year Prosima Data Conference Call.
ETH.MESH.02603812-821 - Dissection Techniques in Transvaginal Pelvic Organ Prolapse Repair with Synthetic Mesh
ETH.MESH.02656825-834 - Issue Report Pence FN 218 TVT-O 2010
ETH.MESH.02658316 - Cover Letter
ETH.MESH.02658317-352 - Postmarket Surveillance Study No. PS120043; Gynecare Prolift +M Pelvic Floor Repair Systems; Gynecare Prolift Pelvic Floor Repair Systems

Production Materials

ETH.MESH.02967410 to ETH.MESH.02967412 Study: Prosima (300-06-005); Plots/charts for 12-month vs. baseline safety analysis set.
ETH.MESH.03048942 to ETH.MESH.03048942 Document entitled "New" Mint January 05, 2006.
ETH.MESH.03049774 to ETH.MESH.03049775 Gynecare Prosima* Combined Pelvic Floor Repair System: Clinical Strategy.
ETH.MESH.03056578 to ETH.MESH.03056580 Email string from Colin Urquhart to David Robinson and Judith Gauld re: Prosima* investigator bulletin.
ETH.MESH.03109341 to ETH.MESH.03109341 Email string, top one from Judi Gauld to Halina Zyczynski re: Prosima well received at AUA.
ETH.MESH.03160821 to ETH.MESH.03160821 Email from Judith Gauld to Allison London Brown re: US Prosima Sites; cc: David Robinson, et al.
ETH.MESH.03160822 to ETH.MESH.03160823 Email string, top one from Judith Gauld to Stephanie Kute re: MINT Design Validation Dates; cc: Dan Smith, et al.
ETH.MESH.03160827 to ETH.MESH.03160828 Email string, top one from Colin Urquhart to Stephanie Kute re: Doctors contacted for DVal as of today; cc: Judith Gauld, et al.
ETH.MESH.03162936 to ETH.MESH.03162938 Email string from Judith Gauld to David Robinson and Jonathan Meek re: Marcus Carey US visit.
ETH.MESH.03259439-40 - 4.24.2009 Gauld email chain re Green Journal
ETH.MESH.03361293 - Mesh Platform Review: Somerville, November, 2010.
ETH.MESH.03393725 to ETH.MESH.0339731 Sikirica, V, et al. "Sexual Function 12 Months Following Vaginal Prolapse Repair Augmented by Mesh and a Vaginal Support Device" ICS/IUGA (2010) Abstract
ETH.MESH.03396246 to ETH.MESH.03396246 VSD Patient Information (Slim Jim) - "Stop Coping Start Living."
ETH.MESH.03427757 to ETH.MESH.03427759 EWHU eClinical Compendium - Article Summary. Barber, M.D., et al. "Transobturator Tape Compared with Tension-free Vaginal Tape for the Treatment of Stress Urinary Incontinence: A Randomized Controlled Trial.
ETH.MESH.03427878-883 - TVT IFU - (11.29.10 to 11.26.14)
ETH.MESH.03439842 to ETH.MESH.03439846 Prosima Sales Aid Training Deck - "What could a truly tension-free repair mean for you and your patients?"
ETH.MESH.03440816 to ETH.MESH.03440836 Prosima Revised Webinar Deck - Overview
ETH.MESH.03458123-38 - TVT Patient Brochure
ETH.MESH.03460813-853 - Prolift Surgeon's Resource Monograph, approved 4.13.2007
ETH.MESH.03463398-407 - Email from Stacy Hoffman to Mary Byerly August 12, 2010 RE: FW: Urogynecological urinary incontinence product contract
ETH.MESH.03466382-83 - Email string dated 5/12/2011, top one from Kevin Frost to Benjamin Bouterie re: Dr. Bedestani; cc: Stacy Hoffman
ETH.MESH.03471308 - Chart entitled "Pedm Monthly Status."
ETH.MESH.03497846-47 - MD&D Complaint Pence FN 216
ETH.MESH.03612364 to ETH.MESH.03612364 Gynecare Prosima Pelvic Floor Repair Preceptorship, Course Overview.
ETH.MESH.03626267 to ETH.MESH.03626269 Email string, top one from Jennifer Paradise to Susie Chilcoat re: Prosima Professional Education Slide Deck Conference Call.
ETH.MESH.03643392 to ETH.MESH.03643395 Email string, top one from Jennifer Paradise to Adrian Roji, et al. re: Approved for distribution: FDA Notification FAQs and Customer Letter.
ETH.MESH.03649244-249 - Risk Management Report TVT SECUR System

Production Materials

ETH.MESH.03667696 – Company Procedure for US Regulatory Affairs Review of Promotion and Advertising Material for Medical Devices
ETH.MESH.03714002-018 - Martin Weisberg Clinical Report on TVT-S 12.2.05
ETH.MESH.03714599-614 - Martin Weisberg Clinical Report on TVT-S
ETH.MESH.03715978 - Weisberg email re: TVT question.
ETH.MESH.03736120-127 - Gynemesh PS: A New Mesh for Pelvic Floor Repair Early Clinical Experience
ETH.MESH.03895925-26 - Email from Frost to Affeld, et al. re: Sales Rep Training on Prosima 5/18
ETH.MESH.03905472-77 - Email string re-TVT recommendation from Dr. Alex Wang
ETH.MESH.03905619-621 - Email from Martin Weisberg to Patirica Hojnoski September 15, 2005 RE: Clinical Expert Report
ETH.MESH.03905968-975 - Prolift Patient Brochure: POP, Get the facts, be informed, make your best decision
ETH.MESH.03905976-991 - Prolift Patient Brochure: POP, Get the facts, be informed, make your best decision
ETH.MESH.03906001-20 - Patient Brochure: What You Should Know About Pelvic Organ Prolapse. Stop Coping. Start Living. Dated 11/9/2009
ETH.MESH.03906037-052 - Prolift Patient Brochure: Treatment Options for POP, stop coping, start living
ETH.MESH.03907468-9 - Second Generation TVT - by Axel Arnaud
ETH.MESH.03910175 - Email string re - Soft Prolene
ETH.MESH.03910418-21 - Email string re-Mini TVT - mesh adjustment
ETH.MESH.03911107-08 - Email string re-TVT complications (an Prof. Hausler)
ETH.MESH.03911901-910 - Deprest J, et al. The biology behind fascial defects and the use of implants in pelvic organ prolapse repair. Int Urogynecol J (2006)
ETH.MESH.03913357-359 - Axel Arnaud Email 5.31.07 Re TVT TVT-O
ETH.MESH.03916905-13 - Plaintiff's Exhibit 3827
ETH.MESH.03917375-378 - (11.26.2002) Email string, top one from Martin Weisberg to Dr. Richard Juraschek, et al. re: Mini TVT - mesh adjustment.
ETH.MESH.03921355-156 - Miller, D. Prospective Clinical Assessment of the Total Vaginal Mesh (TVM) Technique for Treatment of Pelvic Organ Prolapse - 6 and 12 month results.
ETH.MESH.03921836-838 - Email from Laurent Metz to Sheri Dodd RE: TVT - Secur Registry - Local Activities
ETH.MESH.03922483-484 - Email from Andrew Beveridge to DL-JNJFRIS EWHU Umbrellas April 26, 2007 RE: GYNECARE TVT SECUR* System Wins Medical Design Excellence Award
ETH.MESH.03924557-86 - Meshes in Pelvic Floor Repair-Findings from literature review and conversations-interviews with surgeons, June 6, 2000.
ETH.MESH.03930120-123 - Nilsson C. Seven-Year Follow-up of the Tension-Free Vaginal Tape Procedure for Treatment of Urinary Incontinence. Obstet Gynecol 2004; 104(6): 1259-62
ETH.MESH.03932909-911 - Confidential - History of TVT-O
ETH.MESH.03932912 - The History of TVT
ETH.MESH.03932912-14 - History of TVT
ETH.MESH.03941623 - DeLeval Email RE: TVT ABBREVO ALERT - French and English Email and English Translation Certification Plaintiff's Exhibit 3619- Perry
ETH.MESH.03959337 - Prolift+M vs. Prosima - 2 year results
ETH.MESH.03962244 - Dear Surgeon letter 7/18/11

Production Materials

ETH.MESH.03984409 to ETH.MESH.03984410 Email string, top one from Scott Finley to Greg Prine re: Pelvic Floor Repair Customer Meeting.
ETH.MESH.03989722 to ETH.MESH.03989723 Email string, top one from Jim Gatewood to Rebecca Ryder re: Prosima 2 Year data Dinner.
ETH.MESH.03989781 to ETH.MESH.03989782 Email from Jim Gatewood to Marilyn Valdes re: Norfolk, VA, Dec 2, 2010 Prosima Awareness Dinner Information.
ETH.MESH.03991591 to ETH.MESH.03991592 Memo re: Gynecare Studies; created by Randall Gore.
ETH.MESH.04005090-91 - Ethicon informs FDA of discontinuation
ETH.MESH.04005092-93 - Ethicon's Notification to FDA to Decommercialize
ETH.MESH.04005095-96 - Ethicon's Notification to FDA regarding Decommercialization
ETH.MESH.04042511 to ETH.MESH.04042512 Slack, M., et al. Presentation Title: "Clinical Experience of a Novel Vaginal Support Device and Balloon used to Simplify Mesh Augmented Vaginal surgery for Prolapse."
ETH.MESH.04046302 - Gynecare TVT Tension-free Support for Incontinence and Gynecare TVT-O Tension-free Support for Incontinence Update
ETH.MESH.04048515-520 - Carl Nilsson KOL Interview Project Scion 06.18.08
ETH.MESH.04077172 to ETH.MESH.04077172 Powerpoint: Gynecare LatAm Moments at IUGA Congress 2010
ETH.MESH.04081189 - Meeting Agenda
ETH.MESH.04081189-190 - Meeting Agenda
ETH.MESH.04082973 - Possible Complications for Surgeries to Correct POP and SUI
ETH.MESH.04092868 - Email re : 10100080654 and TVT IFUs
ETH.MESH.04093125 - Email from Meng Chen to Bryan Lisa January 29, 2009 RE: FW: TVT IFUs on tape extrusion, exposure and erosion
ETH.MESH.04099233-234 - Email from Melissa Day to Luis Blanco September 24. 2008 RE: #1010078150
ETH.MESH.04126903-906 - Email from Jan Law to Aran Maree November 8, 2007 RE: Hi Jan, I didn't hear back from Malcom at all yesterday. Any chance of this morning? I am at ELT meeting but mobile and e mail are on.
ETH.MESH.04201880 - Prosima Training Deck 2
ETH.MESH.04381806 to ETH.MESH.04381819 Literature Review on Biocompatibility of Prolene Sutures and Impants
ETH.MESH.04427456 to ETH.MESH.14427457 FDA Letter re: K063562 Gynecare Prosima Pelvic Floor Repair Systems
ETH.MESH.04474731 - Ethicon's Cover Letter Response to TVT Secur 522 Order
ETH.MESH.04474733 - Ethicon's TVT Secur Postmarket Surveillance Study Plan: {S120095; Gynecare TVT Securm System
ETH.MESH.04476265-72 - April 24 2012 email to FDA
ETH.MESH.04476274-75 - Email re: Meeting Minutes from April 18 2012 meeting w FDA
ETH.MESH.04543334 - Email re: Faculty & Customer Call Post-FDA Panel Mtg on 9/12
ETH.MESH.04543335 Pelvic Organ Prolapse Surgical Mesh Discussion call in information 9/12/11
ETH.MESH.04543336 Pelvic Organ Prolapse Surgical Mesh Discussion call in information 9/12/11
ETH.MESH.04548931-35
ETH.MESH.04548975 - Email re: Piet's response to 522 FDA refusal clean
ETH.MESH.04550996-97 Email string, top one from Piet Hinoul to Marcus Carey and Richard Gooding re: Prosima VSD on market.

Production Materials

ETH.MESH.04551757-95 E-mail with attachment from Piet Hinoul to Jeffrey Hammond, Dr. James Hart, et al. regarding Benefit risk profile TVM
ETH.MESH.04551946 Ethicon Gynecare WW Commercialization Decision - US Surgeon Letter 6/1/12
Eth.Mesh.04554662 Ethicon Gynecare WW Commercialization Decision - US Frequently Asked Questions 6/1/12
ETH.MESH.04554687 - FDA letter to Ethicon re 522 Orders (Kanerviko 2013-08-22 29)
ETH.MESH.04556236 - Email re: Piet's takeaways from 2011 FDA meeting
ETH.MESH.04558399-409 - Iglesia C. Vaginal Mesh for Prolapse: A Randomized Controlled Trial. Obstet Gynecol 2010;116:293-303
ETH.MESH.04567040-44 - FDA's Response to proposed study plan-04.02.2012
ETH.MESH.04567080 - FDA's Resposne to Discontinuation and Agreement to Hold 522 Responses
Eth.Mesh.04567174 Ethicon Gynecare US Commercialization Decision - US Discussion Guide for Use with Customers 5/15/12
Eth.Mesh.04567674 Ethicon Gynecare US Commercialization Decision - Core Messages 5/15/12
Eth.Mesh.04567677-79 Frequently asked questions 5/15/12
Eth.Mesh.04567680-81 Message from Laura Angelini to Internal WW Associates 5/15/12
Eth.Mesh.04567686-79 US Sales Call Script for Matt Henderson 5/15/12
Eth.Mesh.04567695 Ethicon Gynecare WW Commercialization Decision - Core Messages 6/1/12
Eth.Mesh.04567698 Ethicon Gynecare WW Commercialization Decision - Standby Statement 6/1/12
Eth.Mesh.04567707 Ethicon Gynecare WW Commercialization Decision - Chuck Austin Message to WW General Surgery Employees 6/1/12
Eth.Mesh.04567726 Ethicon Gynecare WW Commercialization Decision - Tim Schmid message to US General Surgery Employees 6/1/12
ETH.MESH.04568448 - Email re: Piet following 2011 Ad Com
ETH.MESH.04568519 - Email dated 6/8/2012 from Matt Henderson to Tim Schmid re: 522 Communication Recap
ETH.MESH.04568519 to ETH.MESH.04568519 Email from Matt Henderson to Tim Schmid re: 522 Communication Recap.
ETH.MESH.04568717-18 - Email from Tim Schmid to Chuck Austin dated 6/8/12 re: Prolift +M withdrawal notice
ETH.MESH.04925553-91 - Postmarket Surveillance Study PS120044, Gynecare Prosima™ Pelvic Floor Systems - K063562 dated 2/1/2012
ETH.MESH.04926191-92
ETH.MESH.04927339-40 - FDA's Resposne to Discontinuation Notification-07.09.2012
ETH.MESH.04931596 - Kanerviko email re 40000 page response to 522
ETH.MESH.04938298-299 - Piet Hinoul Email Re: Prof. de Leval - TVT Abbrevio
ETH.MESH.04939001 - Letter from Dr. Joerg L. Holste, re: Biocompatibility Risk Assessment for Laser-cut Implant of Gynecare TVT
ETH.MESH.04941016 - Lightweight Mesh Developments (Powerpoint)
ETH.MESH.04945231-239 - Email string re-Ultrapro vs Prolene Soft Mesh
ETH.MESH.04945496 - Bernd Klosterhalfen Email Re: Ultrapro vs. Prolene Soft Mesh April 18, 2005
ETH.MESH.05009194
ETH.MESH.05092843 to ETH.MESH.05092843 Chart listing lab schedule for August 11th.
ETH.MESH.05106233 to ETH.MESH.05106234 Email string, top one from Kevin Frost to danhalt@gmail.com, et al. re: Reminder: Prosima Professional Education Slide Deck Conference Call Tonight 7pm EST.

Production Materials

ETH.MESH.05164225 to ETH.MESH.05164226 EWHU eClinical Compendium - Article Summary. Reisenauer, C., et al. "Anatomic study of prolapse surgery with nonanchored mesg and a vaginal support device."
ETH.MESH.05165675 to ETH.MESH.05165677 EWHU eClinical Compendium - Article Summary. Barber, M.D., et al. "Defining success after surgery for pelvic organ prolapse." Obstet Gynecol (2009) 114:600-609.
ETH.MESH.05217098 to ETH.MESH.05217100 FDA Clearance Letter, Modified PROLENE
ETH.MESH.05217103 to ETH.MESH.05217144 Letter to FDA re: Notification of Intent
ETH.MESH.05225380-384 - TVT IFU - (09.08.00 to 11.26.03)
ETH.MESH.05337217-220 - Email string, top one from D. Miller to J. Paradise, et al
ETH.MESH.05343480 to ETH.MESH.05343482 Email string, top one from Joseph Lanza to Bart Pattyson re: Review EWHU IUGA events.
ETH.MESH.05343757 to ETH.MESH.05343758 Email string, top one from Kevin Frost to Bart Pattyson re: July 31 Heads Up; cc: Lissette Caro-Rosado.
ETH.MESH.05347751-762 - Email string re Investigator-initiated studied policy
ETH.MESH.05404976 - Commerical-in-confidence Update to the TGA on TVT Secur™ 1 May 2008
ETH.MESH.05469908 to ETH.MESH.05469912 Email string, top one from Thomas Barbolt to Dr. Joerg Holste, et al. re: Ultrapro; cc: Laura Angelini, et al.
ETH.MESH.05479411 - The (clinical) argument of lightweight mesh in abdominal surgery
ETH.MESH.05479535
ETH.MESH.05534022 - Revision History for TVT Secur application FMEA
ETH.MESH.05560563-564 - Email from Patricia Hojnoski to Martin Weisberg September 13, 2005 RE: Clinical Expert Report; ETH.MESH.05560579-80 - Email from Patricia Hojnoski to Martin Weisberg September 15, 2005 RE: Clinical Expert Report
ETH.MESH.05571741 to ETH.MESH.05571741 Email string, top one from Jim Gatewood to Robert Zipfel re: Gynecare Prof Ed - Approved: Request for Speaker Event.
ETH.MESH.05573916 to ETH.MESH.05573917 Email string, top one from Kevin Frost to Jennifer Paradise re: Prosima VRT Reminder - Honoraria Payments; cc: Paul Parisi.
ETH.MESH.05588123-126 - Stephen Wohler Email - AW: How inert is polypropylene? July 9, 2007
ETH.MESH.05644163-171 - Pelvic Floor Repair-Surgeon's Feed-back on Mesh Concept
ETH.MESH.05741094 to ETH.MESH.05741094 Email from Rhonda Peebles to Samuel Sheelu, et al. re: Additional room for Ask the Expert sessions; cc: Alyson Wess, et al.
ETH.MESH.05741890 to ETH.MESH.05741891 Email string, top one from Christopher Teasdale to Tom Affeld, et al. re: Additional room for Ask the Experts sessions.
ETH.MESH.05799233-39 - TVT Exact IFU
ETH.MESH.05820723 - Dear Surgeon Letter re Discontinuation
ETH.MESH.05835298 to ETH.MESH.05835308 Pelvic Organ Prolapse - Patient Counseling Guide.
ETH.MESH.05837063 to ETH.MESH.05837110 Pelvic Organ Prolapse Value Dossier. Gynecare Prolift, Gynecare Prolift +M, Gynecare Prosima.
ETH.MESH.05840629 to ETH.MESH.05840629 Powerpoint Presentation entitled "Continuum of Education."
ETH.MESH.05918776 - Email re: Marlex Experience
ETH.MESH.05922038 to ETH.MESH.05922038 Letter from Patricia Nevar to Jaime Sepulveda, M.D. re: Secrecy Agreement for Prosima.
ETH.MESH.05947160 to ETH.MESH.05947163 Email from Patricia Holland to Andre Fontes re: Partnership Plus Follow up_Gynecare_Reminder; cc: Fernando Nassif, et al.
ETH.MESH.05958248 - Surgeons Resource Monograph

Production Materials

ETH.MESH.05967586 to ETH.MESH.05967587 Email string, top one from Robert Zipfel to Susie Chilcoat re: Prosima Preceptor-Led Virtual Round Tables (VRTs) faculty payment.
ETH.MESH.05987605-06 - Email re: Piet's response to 522 FDA refusal
ETH.MESH.05998835-836 - Piet Hinoul Email Re: ALERTE TVT ABBREVO
ETH.MESH.06050509 - Email from Aran Maree to Darryl Harkness November 20, 2007 RE: TVT Secur discussions Somerville Tues 20 Nov
ETH.MESH.06050795-796 - Memo to TVT Secure DHF #0000120 from Gary Borkes RE: TVT Secur 12 month post launch review August 17, 2007
ETH.MESH.06113091 to ETH.MESH.06113092 Email from Debra Mayfield to DL-ETHUSSO EWHU WESTERN REGION re: Prosima VRT Invitation Plan - due Jan 28.
ETH.MESH.06124656 to ETH.MESH.06124657 Email string, top one from Andrew Meek to Bart Pattyson re: Prosima training.
ETH.MESH.06124954 to ETH.MESH.06124955 Email string, top one from Bart Pattyson to Marcos Fujihara re: Prosima training in Miami with Dr. Jaime Sepulveda.
ETH.MESH.06125000 to ETH.MESH.06125001 Email string, top one from Bart Pattyson to Robert Zipfel re: Prosima in LATAM.
ETH.MESH.06125058 to ETH.MESH.06125058 Email from Bart Pattyson to Eugene Brohee re: June 21 - Latin America doctors in town; cc: Selena Lessa.
ETH.MESH.06125098 to ETH.MESH.06125098 Email string, top one from Bart Pattyson to Georgia Long re: updated agenda - May 8th.
ETH.MESH.06125277 to ETH.MESH.06125277 Email string, top one from Marcos Fujihara to Bart Pattyson, et al. re: Prosima presentation in Miami.
ETH.MESH.06125309 to ETH.MESH.06125309 Email string, top one from Robert Zipfel to Bart Pattyson re: Prosima in LATAM.
ETH.MESH.06125502 to ETH.MESH.06125502 Email string, top one from Georgia Long to Bart Pattyson re: may 8th.
ETH.MESH.06151466 to ETH.MESH.06151467 Email string, top one from David Robinson to Judith Gauld re: Jaime Sepulveda.
ETH.MESH.06238611 to ETH.MESH.06238611 Email from Mark Kenyon to Aaron Kirkemo re: NEO Surgical Guide - Role & Responsibilities; cc: Vincenza Zaddem.
ETH.MESH.06255523 to ETH.MESH.06255534 Gynecare Prosima™ Pelvic Floor Repair System. "An Expert Interview with Dr. Marcus P. Carey, MBBS, FRANZCOG, CU, the Inventor of the Gynecare Prosima System."
ETH.MESH.06382976-987 - Jia, X. Efficacy and safety of using mesh or grafts in surgery for anterior and/or posterior vaginal wall prolapse: systematic review and meta-analysis. BJOG 2008; 115: 1350-1361
ETH.MESH.06388151 to ETH.MESH.06388151 Powerpoint: Prolift Pelvic Floor Repair - MDV Reported Complaints
ETH.MESH.06480608 to ETH.MESH.06480609 Email string, top one from Judith Gauld to Stephanie Kute re: MINT Design Validation Dates; cc: Dan Smith, et al.
ETH.MESH.06482821 to ETH.MESH.06482822 Email from Judith Gauld to Tony Smith re: Prosima Investigator Meeting; cc: David Robinson.
ETH.MESH.06585815 to ETH.MESH.06585815 Powerpoint: Agenda
ETH.MESH.06591558 to ETH.MESH.06591559 Email string, top one from Tom Affeld to Shwetal Narvekar re: Pre-launch Awareness for Prosima with Dr. Marcus Carey; cc: Bart Pattyson, et al.
ETH.MESH.06592243 - 09.14.2012 Email from Carl Nilsson to Laura Angelini

Production Materials

ETH.MESH.06695438 - Justification for Utilizing the Elasticity Test as the Elongation Requirements on TVT LCM
ETH.MESH.06769156 to ETH.MESH.06769156 Powerpoint: A New Operation for Vaginal Prolapse Repair Using Mesh and a Vaginal Support Device: 1 Year Anatomic and Functional Results of an International, Multicenter Study. Mark Slack, Cambridge, UK for the Prosima Study Group.
ETH.MESH.06887138-40 - Waltregny email written on behalf of Professor de Leval.
ETH.MESH.06887244 - 07.16.04 David Waltregny email to Dan Smith re: TVT-O.
ETH.MESH.06917699-704 - Form For Customer Requirements Specification (CRS) For Project TVT-O PA
ETH.MESH.06923868-71 - TVTO-PA Clinical Strategy - 8.21.13 Exhibit A.M. Mitchell T-2177
ETH.MESH.0706066 - Clinical Evaluation Report for the TVT SECUR signed by David Robinson on 2/28/12
ETH.MESH.07105727 to ETH.MESH.07105727 Email string, top one from Laura Vellucci to Colin Urquhart re: Prosima publication.
ETH.MESH.07189091 to ETH.MESH.07189091 Powerpoint: From presentation to publication: ensuring quality in the reporting of urogynaecology research. IUGA "This house believes that industry sponsorship has a corrosive influence on standards of scientific reporting." Conflict of interests: Piet Hinoul, M.D.
ETH.MESH.07190144 to ETH.MESH.07090145 Email string, top one from Judi Gauld to Piet Hinoul, Colin Urquhart re: +M Abstract.
ETH.MESH.07192929 - Investigating Mesh Erosion in Pelvic Floor Repair Powerpoint
ETH.MESH.07201006 - Prolift Professional Education Slide Deck (2007)
ETH.MESH.07219196 to ETH.MESH.07219209 Clinical Expert Report - Prosima™ signed by David Robinson.
ETH.MESH.07226579-590 - 2000 - TVT CER
ETH.MESH.07229215 to ETH.MESH.07229245 Clinical Expert Report - Prosima™ signed by Piet Hinoul.
ETH.MESH.07229312-42 - Clinical Expert Report Gynecare Prosima™ Pelvic Floor Repair System signed by Piet Hinoul dated 9/25/2012
ETH.MESH.07296496 to ETH.MESH.07296496 Chart listing Week Schedule and Lab Flow.
ETH.MESH.07308636 to ETH.MESH.07308637 Email from Tom Affeld to Clifford Volpe, et al. re: Surgeon's view on Prosima; cc: Lissette Caro-Rosado, et al.
ETH.MESH.07324554-55
ETH.MESH.07351297 - Application FMEA for TVT Classic Doc# FMEA-0000536 Rev.<1>
ETH.MESH.07374762 to ETH.MESH.07374763 Email from Lissette Caro-Rosado to Jaime Sepulveda, et al. re: Pelvic Floor Advisory Board; cc: Bart Pattyson, et al.
ETH.MESH.07379573 to ETH.MESH.07379574 Email string, top one from Kevin Frost to Ahmet Bedestani, et al. re: Purpose; cc: Matt Henderson, et al.
ETH.MESH.07383730-31 - Email string re-Ultrapro mesh information-identical mesh to Prolift +M
ETH.MESH.07384790 to ETH.MESH.07384791 Email string, top one from Robert Zipfel to Lissette Caro-Rosado re: Prosima and Advanced Prolift Preceptorship with Dr. Sepulveda and Drs. Antar, Jones, and Schlafstein on Monday Jan 4, 2010.
ETH.MESH.07396541-546 - Procedural Pearls & Frequently Asked Questions
ETH.MESH.07452663 - Ethicon Powerpoint Neuchatel, particles in TVTO Blisters Pence FN 219
ETH.MESH.07453752-57 - Email from Shalot Armstrong dated 9.1.10
Eth.Mesh.07462313 Email from Adrian Roji dated 8/19/11 re update message to the field re FDA notification response

Production Materials

ETH.MESH.07587090 to ETH.MESH.07587091 Email string, top one from Judith Gauld to Patricia Nevar re: Dr. Sepulveda; cc: Colin Urquhart.
ETH.MESH.07628243 to ETH.MESH.07628243 EWH&U Gynecare Prosima™ Pelvic Floor Repair System Faculty Checklist.
ETH.MESH.07630654 to ETH.MESH.07630654 Email string, top one from Greg Prine to Stevan Barendse, Robert Zipfel re: Prosima targets.
ETH.MESH.07631488 to ETH.MESH.07631488 Email string, top one from Selena Lessa to Robert Zipfel re: Prosima course with Sepulveda.
ETH.MESH.07631752 to ETH.MESH.07631753 Email string, top one from Eric Globerman to Nicole Huffman re: Prosima course; cc: Robert Zipfel.
ETH.MESH.07631967 to ETH.MESH.07631968 Email string, top one from Stacy Hoffman to Robert Zipfel, Kimberly Heath re: Prosima Lab.
ETH.MESH.07632042 to ETH.MESH.07632042 Event request form for Sepulveda Preceptorship.
ETH.MESH.07632042 to ETH.MESH.07632043 Email from Kevin Frost to danhalt@gmail.com, et al. re: Save the Date: Prosima Faculty Conference Call 7/20 at 7pm EST; cc: Jennifer Paradise.
ETH.MESH.07634049
ETH.MESH.07636090 to ETH.MESH.07636090 Prosima Cadaver Lab Invitation
ETH.MESH.07653362 to ETH.MESH.07653363 Email string, top one from Tommaso Santini to Kevin Frost, et al. re: US Surgeon; cc: Tom Affeld.
ETH.MESH.07876748 - A 3 month pre-clinical trial to assess the fixation force of a new TVT (TVT _x) in the sheep model
ETH.MESH.07931680 to ETH.MESH.07931681 Email string, top one from Bart Pattyson to Jeff Hsieh re: Prosima Professional Education Slide Deck Conference Call.
ETH.MESH.07951163 to ETH.MESH.07951163 Document re: Prosima's apical/anatomical success rates and functional outcomes.
ETH.MESH.07953429 to ETH.MESH.07953433 EWH&U 2011 Field Visit Letter
ETH.MESH.07977911
ETH.MESH.08003181-96 - TVT Patient Brochure
ETH.MESH.08003231-46 - TVT Patient Brochure
ETH.MESH.08003263-278 - TVT Secur IFU
ETH.MESH.08003279-294 - TVT Secur IFU
ETH.MESH.08003279-94 - TVT Patient Brochure
ETH.MESH.08003295-302 - TVT Patient Brochure
ETH.MESH.08021804 to ETH.MESH.08021807 Email string, top one from Libby Lewis to Kenneth Pagel, et al. re: Journal Club - trocar-less vaginal mesh kits.
ETH.MESH.08023741 to ETH.MESH.08023744 Email string, top one from Scott Miller to Jonathan Fernandez re: Prosima Take Away Messages.
ETH.MESH.08033153 to ETH.MESH.08033153 Document entitled "Prevalence and risk factors for mesh erosion after laparoscopic-assisted sacrocolpopexy." Author(s) Jasmine Tan-Kim, Shawn A, Menefree, Karl M, Lubner, Charles W. Nager, Emily S. Lukacz.
ETH.MESH.08048738 to ETH.MESH.08048740 Email from David Jackson to Selena Lessa re: Prosima course with Sepulveda.
ETH.MESH.08066452 to ETH.MESH.08066452
ETH.MESH.08107354 - Gynecare TVT Tension-free Support for Incontinence: Professional Education Slides
ETH.MESH.08135444 to ETH.MESH.08135444 Gynecare Prosima - Pelvic Floor Repair System Proctorship

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ETH.MESH.08139049 to ETH.MESH.08139118 Pelvic Organ Prolapse - The Role of Prosima. Author: Mark Slack.
ETH.MESH.08161765 to ETH.MESH.08161765 Email from Suzy Taylor to Jared Aldridge, et al. re: Follow up to FDA Mesh Advisory.
ETH.MESH.08169582 to ETH.MESH.08169620 Surgical Practice of POP survey on Survey Monkey.
ETH.MESH.08290691 to ETH.MESH.08290691
ETH.MESH.08299913-917 - Nilsson C. Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J 2013; 24(8): 1265-9 [9.11.13 Exhibit T-1271]
ETH.MESH.08309057 to ETH.MESH.08309092 Document entitled "Benefit-Risk Profile of Ethicon, Inc.'s Pelvic Organ Prolapse Mesh Repair Products."
ETH.MESH.08315779 - Clinical Expert report-09.25.2012
ETH.MESH.08315779-810 - Clinical Expert Report Gynecare Prolift+M™ Pelvic Floor Repair System signed by Piet Hinoul dated 9/25/2012
ETH.MESH.08334244; ETH.MESH.08334245 - Email re Photographs of LCM vs MCM with attachments
ETH.MESH.08334244-45 - Email string re-Photographs of LCM vs MCM with powerpoint attachment
ETH.MESH.08375158 to ETH.MESH.08375159 Email string, top one from Larry Gillihan to Kenneth Pagel, Jason Hernandez re: New Product Tabs - TVT Abbrevio, Prosima, TVT Exact.
ETH.MESH.08384247 to ETH.MESH.08384247
ETH.MESH.08384270 to ETH.MESH.08384270 Email string, top one from Lisa Pitts to Paul Saliba re: Prosima pearls from Dr. Garris.
Eth.Mesh.08421628 Ethicon Gynecare WW Commercialization Decision - US Customer Discussion Guide 6/1/12
ETH.MESH.08492824 to ETH.MESH.08492824 Strategic Business Team Meeting - Meeting Notes
ETH.MESH.08565137-41
ETH.MESH.08640676 Jones email 4/04/08 re Prosima update for RBDs
ETH.MESH.08791917
ETH.MESH.08918949-52 - Email from Shalot Armstrong dated 9.1.10
ETH.MESH.08945734 to ETH.MESH.08945735 ICS-IUGA 2010 Abstract Form. "Ultrasound assessment 6 months following vaginal prolapse surgery using polypropylene implants and a vaginal support device."
ETH.MESH.08945742 to ETH.MESH.08945744 Presentation Title: A New Operation for Vaginal Prolapse Repair using Mesh and a Vaginal Support Device: 1 Year Anatomic and Functional Results of an International, Multicentre Study." Presenter: Slack, M., et al.
ETH.MESH.08945836 to ETH.MESH.08945840 Document entitled "Gynecare Prosima Claims List."
ETH.MESH.08948364 to ETH.MESH.08948365 Email string, top one from Kevin Frost to William Rush re: Save the Date: Prosima 2 Year Clinical Data Review; cc: Tom Affeld.
ETH.MESH.08951725 to ETH.MESH.08951726 Email string, top one from Tom Affeld to Kevin Froser re: Prosima 2 year summary for eClinical Compendium.
ETH.MESH.08961175-76
ETH.MESH.08962682 to ETH.MESH.08962683 Email from Helen Wong to Kevin Frost re: Sepulveda's comment on the VRT; cc: Jenny Krieger, et al.
ETH.MESH.08962684 to ETH.MESH.08962685 Email string, top one from Jenny Krieger to Kevin Frost re: Reminder: Prosima Teleconference today.
ETH.MESH.08971152 to ETH.MESH.08971153 Email string, top one from Kevin Frost to Libby Lewis re: Prosima VRT Invitation plan - due Jan 28.

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ETH.MESH.08971269 to ETH.MESH.08971270 Email string, top one from Kevin Frost to Aaron Kirkemo, Piet Hinoul re: Prosima VRT: fill-in.
ETH.MESH.08971271 to ETH.MESH.08971272 Email string, top one from Kevin Frost to Marilyn Valdes re: Dr. Sepulveda availability on 1/31.
ETH.MESH.08971309 to ETH.MESH.08971314 Email string, top one from Kevin Frost to Helen Wong re: Dr. Sepulveda's 1/31 VRT; cc: Jenny Krieger.
ETH.MESH.08988155 to ETH.MESH.08988155 Powerpoint: Gynecare Prosima™ Pelvic Floor Repair System: Background. Halina Zyczynski, M.D.
ETH.MESH.08988298 to ETH.MESH.08988417 EBM - Pelvic Organ Prolapse Clinical References: 2002-2011, including Prolift, Prolift+M, Prosima, Gynemesh. Searcher: Kerry Kushinka.
ETH.MESH.09050450 to ETH.MESH.09050450 Memorandum from David Robinson re: the compatibility if estrogen creams with Prosima balloon and vaginal support device. (Not signed).
ETH.MESH.09100506 - Prolift Professional Education Slide Deck (2005)
ETH.MESH.09128451 to ETH.MESH.09128451 Chart entitled "Faculty Training."
ETH.MESH.09128545 Pelvic Organ Prolapse Surgical Mesh Discussion call in information 8/25/11
ETH.MESH.09138054 to ETH.MESH.09138055 Information re: Jaime Sepulveda, M.D. and Arthur Mourtzinis, M.D.
ETH.MESH.09142383 to ETH.MESH.09142384 Email from Kevin Frost to danhalt@gmail.com, et al. re: Save the Date: Prosima Faculty Conference Call 7/20 at 7pm EST; cc: Jennifer Paradise.
ETH.MESH.09142511 to ETH.MESH.09142511 (Draft) EWHU Memo from Bart Pattyson (US Marketing and Professional Education) to US Faculty Members re: Gynecare Prosima - Pelvic Floor Repair System, Updated Professional Education Deck.
ETH.MESH.09144349 to ETH.MESH.09144349 Powerpoint: Ethicon Women's Health and Urology: Clinical Expertise Road Map.
ETH.MESH.09191424 to ETH.MESH.09191426 Email string, top one from Hemangini Patel to Carolina Guzman re: Final Draft report for Prosima - Urgent; cc: Irene Leslie, Rosangela Ribeiro.
ETH.MESH.09207059 to ETH.MESH.09207059 Chart entitled "Grier."
ETH.MESH.09218452 to ETH.MESH.09218453 Email string, top one from Rhonda Peebles to Andrew Meek re: Remaining 2010 labs; cc: Kevin Frost, et al.
ETH.MESH.09238537-541 - Memo to TVT Secure DHF #0000120 from Gary Borkes RE: TVT Secur 12 month post launch review August 17, 2007
ETH.MESH.09264945-46 - Prolene Mesh Re-Design Project
ETH.MESH.09283030 to ETH.MESH.09283030 Spreadsheet re: Open Incontinence & AP.
ETH.MESH.09283031 to ETH.MESH.09283031 Spreadsheet re: Open Incontinence & AP.
ETH.MESH.09283032 to ETH.MESH.09283032 Spreadsheet re: Pelvic Floor Repair
ETH.MESH.09283033 to ETH.MESH.09283033 Spreadsheet re: Budget Summary
ETH.MESH.09283034 to ETH.MESH.09283034 Spreadsheet re: Integrated Marketing
ETH.MESH.09283035 to ETH.MESH.09283035 Spreadsheet re: Summary
ETH.MESH.09283036 to ETH.MESH.09283036 Spreadsheet re: Pelvic Floor Repair
ETH.MESH.09283037 to ETH.MESH.09283037 Spreadsheet re: Budget Summary
ETH.MESH.09283038 to ETH.MESH.09283038 Spreadsheet re: Integrated Marketing
ETH.MESH.09290755 to ETH.MESH.09290755 Spreadsheet re: Q1 2012 Open PO Summary
ETH.MESH.09290760 to ETH.MESH.09290760 Spreadsheet re: Open Incontinence & AP.
ETH.MESH.09290767 to ETH.MESH.09290767 Spreadsheet re: Uterine Health
ETH.MESH.09290769 to ETH.MESH.09290769 Spreadsheet re: Ethicon Gynecare May 2012 Open PO Summary
ETH.MESH.09290772 to ETH.MESH.09290772 Spreadsheet re: Budget Summary

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ETH.MESH.09300480 to ETH.MESH.09300480 Spreadsheet re: Prosima All Day
ETH.MESH.09625725 to ETH.MESH.09625729 Government Submissions Log Sheet
ETH.MESH.09625731 to ETH.MESH.09625737 FDA Letter. re: approved drug application for polypropylene suture.
ETH.MESH.09625816 to ETH.MESH.09625816 FDA letter re: receipt of drug application for polypropylene suture.
ETH.MESH.09625817 to ETH.MESH.09625817 Letter to FDA re: new drug application for Polypropylene Suture.
ETH.MESH.09629447 to ETH.MESH.09629448 FDA Labeling Approval for Prolene
ETH.MESH.09630649 - 4.26.1973 FDA Letter RE: NDA 16-374
ETH.MESH.09630649 to ETH.MESH.09630649 FDA Letter re: package insert for Prolene.
ETH.MESH.09634081 to ETH.MESH.09634081 Sections 6 re: adverse effects.
ETH.MESH.09634299 to ETH.MESH.09634303 FDA Letter re: approval of PMA supplement.
ETH.MESH.09634318 to ETH.MESH.09634318 Prolene Package Insert.
ETH.MESH.09634662 to ETH.MESH.09634663 FDA Letter re: reclassification of Nonabsorbable Polypropylene Surgical Suture.
ETH.MESH.09634664 to ETH.MESH.09634688 FDA Letter re: reclassification of Nonabsorbable Polypropylene Surgical Suture.
ETH.MESH.09656792
ETH.MESH.09656795
ETH.MESH.09744858-63 - TVT Patient Brochure
ETH.MESH.09746948-998 - License and Supply Agreement [Rosenzweig Exhibit 21 - 12.22.15]
ETH.MESH.09747038-097 - Medscand Agreement
ETH.MESH.09747337-369 - Asset Purchase Agreement
ETH.MESH.09888187-223 - Seven Year Data for Ten Year Prolene Study - Plaintiff's Exhibit 4102
ETH.MESH.09922570-578 - R&D Memorandum of PA Mesh Assessments for TVTO-PA Revision 1
ETH.MESH.10048035 to ETH.MESH.10048036 Email from Mark Pare to Walter Boldish, et al. re: Clinical #2 - Prosima; cc: Elizabeth David, et al.
ETH.MESH.10179518 to ETH.MESH.10179636 Clinical Evaluation Report - Gynecare Gynemesh™ PS Nonabsorbable Prolene™ Soft Mesh signed by Piet Hinoul.
ETH.MESH.10179518-636 - Clinical Evaluation Report - Gynemesh PS signed by P. Hinoul on 04.26.2013
ETH.MESH.10180419-78
ETH.MESH.10220659 - Gynecare TVT Tension-free Support for Incontinence: Advanced Users Forum for the Experienced Clinician
ETH.MESH.10224077 to ETH.MESH.10224077 Email string, top one from Molly Dugan to Greg Prine re: Prosima Lab Feedback; cc: Joseph Drabik.
ETH.MESH.10232708 to ETH.MESH.10232708 Email from Stevan Barendse to Greg Prine re: Prosima targets.
ETH.MESH.10281860 - Tension-Free Midurethral Sling: Market Update.
ETH.MESH.1037447-55 - Clinical Expert Report on Gynecare TVT Secur System
ETH.MESH.10376963
ETH.MESH.10378001-8002
ETH.MESH.10384309-310
ETH.MESH.10399553 to ETH.MESH.10399554 Email from Judi Gauld to Marcus Carey, et al. re: Prosima presentation at AUA; cc: David Robinson, et al.

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ETH.MESH.10608341 to ETH.MESH.10608357 Post Market Surveillance Report. Pelvic Floor Repair Systems. Gynecare Prolift, Gynecare Prolift+M and Gynecare Prosima.
ETH.MESH.10817931 Pelvic Mesh Post-Market Surveillance Orders April 2012
ETH.MESH.10960414 to ETH.MESH.10960414 Email from Christopher O'Hara to Francois Barbe, et al. re: VRT for Prosima.
ETH.MESH.11048537 to ETH.MESH.11048538 Prosima E-blast No. 1 "The Proof of Success."
ETH.MESH.11336474-87 - Ten Year In Vivo Suture Study Scanning Electron Microscopy-5 Year Report - Plaintiff's Exhibit 4111
ETH.MESH.11448841 Conference Participant Report 8/25/11
ETH.MESH.11518663 to ETH.MESH.11518665 Email string, top one from Melissa Doyle to Arthur Mourtzinis re: Agenda for tomorrow's lab.
ETH.MESH.11522550 to ETH.MESH.11522551 Email string, top one from Melissa Doyle to Seth Moskos re: VSD "take home" instructions.
ETH.MESH.11523079 to ETH.MESH.11523079 Email from Melissa Doyle to Walter Boldish, et al. re: Lahey Labs September 18, 2010; cc: Carole Carter-Cleaver.
ETH.MESH.11524125 to ETH.MESH.11524128 Email string, top one from Melissa Doyle to Andrew Meek re: Upcoming Labs - planning.
ETH.MESH.11536046 to ETH.MESH.11536046 Email string, top one from Jonathan Fernandez to Rhonda Peebles re: Remaining 2010 labs; cc: Robert Zipfel, et al.
ETH.MESH.11538048-49 - Email from Frost to Globerman, et al. re: prosima usage northeast
ETH.MESH.11543641 - Powerpoint GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh Awareness Module
ETH.MESH.1189423-39 - Clinical Expert Report on Gynecare TVT Secur System from 2/28/06
ETH.MESH.11905619 to ETH.MESH.11905619 Spreadsheet: Prosima Virtual Roundtable Calls &Targets
ETH.MESH.1210987-95 - Email from Hinoul re: South Africa, TVTO sheaths getting stuck upon removal
ETH.MESH.1222075-79 - Letter to Weisberg/Robinson re: Elongation Characteristics of Laster Cut PROLENE Mesh for TVT, from Kammerer
ETH.MESH.1239657-80 - First Clincial Experience with a Single-incision (TVT-Secur) Tape Procedure for Treatment of Urinary Stress Incontinence
ETH.MESH.12831391-92 - P4128 - IR Microscopy of Explanted Prolene received from Prof. R. Guidoin.
ETH.MESH.12897617 to ETH.MESH.12897678 Clinical Evaluation Report - Prosima™ signed by Piet Hinoul.
ETH.MESH.130950 - (Karram) 004 An Evaluation of the Gynecare TVT Secur* System (Tension Free Support for Incontinence) for the Treatment of SUI
ETH.MESH.13314554 to ETH.MESH.13314554 Email from Laura Hance to Dr. Lowden re: Prosima answer to JP drain and hydrodissection.
ETH.MESH.13450933 - Clinical Evaluation Report for the TVT SECUR System (approved by Piet Hinoul, Dated 9/18/13)
ETH.MESH.134794 - Email re: TVT World Board meeting presentation + TVT World Registry EWHU Board 3/2/09 PowerPoint
Eth.Mesh.13532200 Ethicon Gynecare WW Commercialization Decision - US Sales Call Script 6/1/12
ETH.MESH.13592561 to ETH.MESH.13592561 Prosima Trainee Invitation "Advanced Pelvic Floor Course with Gynecare Prosima"

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ETH.MESH.13618003 to ETH.MESH.13618004 EWHU eClinical Compendium - Article Summary. Reisenauer, C., et al. "Anatomic study of prolapse surgery with nonanchored mesh and a vaginal support device."
ETH.MESH.13618029 to ETH.MESH.13618031 EWHU eClinical Compendium - Article Summary. Zyczynski, H.M., et al. "One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device."
ETH.MESH.13622000 to ETH.MESH.13622070 Prosima Trainee Deck Distribution
ETH.MESH.13635675-96 - 2011 B&W POP & SUI Patient Counseling Guide production copy
ETH.MESH.13645631 to ETH.MESH.13645631 DVD - Thoughts on Prolift+M and Prosima from Drs. Michel Cosson and Marcus Carey.
ETH.MESH.13698543 to ETH.MESH.13698543 Prosima Marketing Material Roll-Out Letter.
ETH.MESH.13698840-59 - Bart Pattyson editorial re prof ed bulletin
ETH.MESH.13699674 to ETH.MESH.13699754 Clinical Study Report: A Prospective, Multi-centre Study to Evaluate the Clinical Performance of the Gynecare Prosima™ Pelvic Floor Repair System as a Procedure for Pelvic Organ Prolapse.
ETH.MESH.13756212 to ETH.MESH.13756218 Clinical study Finding Discussion for Gynecare Prosima™ Pelvic Floor Repair System by Piet Hinoul (Audio Transcript).
ETH.MESH.13756219 to ETH.MESH.13756219 Gynecare Prosima™ Pelvic Floor Repair System MRI Address
ETH.MESH.13756384 to ETH.MESH.13756384 Prosima Virtual Round Table Trainee Confirmation
ETH.MESH.13756409 to ETH.MESH.13756409 Prosima Virtual Round Table Preceptor Follow-up and Invitation.
ETH.MESH.13756416 to ETH.MESH.13756417 Prosima Virtual Round Table Preceptor Confirmation.
ETH.MESH.13869166 to ETH.MESH.13869166 Powerpoint: Mint Project - Pelvic Floor Repair.
ETH.MESH.13907284 - PowerPoint - Particles in TVTO Blisters
ETH.MESH.14427453 to ETH.MESH.14427455 FDA Clearance Letter re: K063562 Gynecare Prosima™
ETH.MESH.14427459 to ETH.MESH.14427543 Letter to FDA re: 510(k) K063562 S1, response to deficiencies email.
ETH.MESH.14427562 to ETH.MESH.14427563 Memo to Prosima Regulatory File. Minutes from Teleconference with FDA for Prosima 510(k).
ETH.MESH.14427564 to ETH.MESH.14427565 FDA Letter re: K063562 Gynecare Prosima Premarket Notification 510(k)
ETH.MESH.14427567 to ETH.MESH.14427569 Email from Nada Hanafi to Patrice Napoda re: K063562 Gynecare Prosima.
ETH.MESH.14427578 to ETH.MESH.14427761 TraditionsI 510(k) Premarket Notification Gynecare Prosima™ Pelvic Floor Repair System.
ETH.MESH.14901753 - Batch Review Lot #3405428 Complaint PI1
ETH.MESH.157010-15 - Procedural Pearls & Frequently Asked Questions for Gynecare TVT Secur System Procedural Pearls: Approved 11/01/06
ETH.MESH.1592121-34 - Gynecare TVT Secur System Design Validation Report #TVTSDVLPD1
ETH.MESH.15958178 to ETH.MESH.15958182 Email string, top one from Brian Luscombe to Tom Affeld re: Approved for distribution: FDA Notification FAQs and Customer Letter.
ETH.MESH.161953-54 - 10/12/1990 Letter from FDA re: N16374, Prolene Polypropylene Nonabsorbable Suture Gynecare TVT Obturator System Sales Materials
Eth.Mesh.16259973 Email from Lisa Jannone dated 1/5/12 re message from Lesley Fronio re update on recent media reports

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ETH.MESH.16350627 to ETH.MESH.16350628 Email string, top one from Piet Hinoul to Paan Hermansson re: key message for upcoming Prosima launch.
ETH.MESH.16352932 to ETH.MESH.16352934 Email from Paan Hermansson to Sonja Willems, et al. re: Great EWH&U success at ICS/IUGA congress in Toronto; cc: Bernhard Fischer, et al.
ETH.MESH.1751069-94 - 09/07/2009 Safety review: TVT and TVT-O procedures
ETH.MESH.17669942 to ETH.MESH.17669942 Email from Robert Zipfel tp Elizabeth David, et al. re: Prosima and Advanced Prolift Preceptorship with Dr. Sepulveda and Drs. Antar, Jones and Schlafstein on Monday Jan 4, 2010.
ETH.MESH.17748760 to ETH.MESH.17748761 E-mail from Kevin Frost regarding 2011 Incontinence & Pelvic Floor Recap
ETH.MESH.1784779-82 - Memo re: TVT-Base & TVT-O Complaint Review for Laser Cut Mesh (LCM) Risk Analysis
ETH.MESH.1784823-28 - Clinical Expert Report
ETH.MESH.1809056-58 - Email re: Important Laser cut mesh update
ETH.MESH.1809080-81 - Memo re: Comparison of Laser-cut and machine-cut TVT Mesh to Meshes from Competetive Devices (BE02004-1641)
ETH.MESH.1815660-64 - Project Mulberry, Preliminary Clinical Diligence Report
ETH.MESH.18844812 to ETH.MESH.18844812 Email from Patrick Kaminski to Robert Zipfel re: Dr. Thomas Antonini; cc: Stevan Barendse.
ETH.MESH.19308264 to ETH.MESH.19308265 Email from Walter Boldish to Stefanie Garbarino re: Prosima cadaver labs.
ETH.MESH.19310234 to ETH.MESH.19310238 Email string, top one from Stefanie Garbarino to Dr. Maxwell re: TVT-O
ETH.MESH.2106139-40 - Email re: Regional Input to Finalize TVT WORLD
ETH.MESH.222852-63 - 12/15/2003, Gynecare Final Report # 03*0740, TVT Obturator System
ETH.MESH.222899-909 - Clinical Expert Report
ETH.MESH.223779-84 - Risk Management Report, TVT Laser Cut Mesh (LCM). Document Number RMR-0000017, Rev. 3
ETH.MESH.2293715-6 - Email from Dan Smith re: NG TVT-O NDP - Outcomes from Kickoff Meeting with Pr. De Leval & Dr. Waltregny
ETH.MESH.262089-123 - Manuscript Draft: (de Leval) Novel surgical technique for the treatment of female stress urinary incontinence: Transobturator Vaginal Tape Inside-Out
ETH.MESH.311792-94 - Email re: Australia update and telephone call with Prof Frazer
ETH.MESH.3208548-49 - Email re: TVT World AE Report
ETH.MESH.3235997-98 - Email re: TVT Secur - Media Standby
ETH.MESH.3364663-66 - Email from O'Bryan re: ifu
ETH.MESH.3365250-1 - Email from Weisberg re: IFU update
ETH.MESH.341006-11 - 11/11/10 Letter from John Young re: Global Regulatory Strategy for TVT IFU (RMC P15506/E) Update (Part II, RA0001-2010, Rev. 1)
ETH.MESH.371496-594 - 01/28/98 Letter from FDA re: K974098 TVT System
ETH.MESH.3911390-1 - Email from Arnaud re: Transient Leg Pain with Mulberry
ETH.MESH.3913651-55 - CDMA Europe Meeting, Urinary Incontinence Platform, Meeting Minutes from 6/1/07
ETH.MESH.3922618-19 - Email re: Conf call tomorrow
ETH.MESH.3922926-28 - Email re: OR Agenda Tunn
ETH.MESH.3934952-67 - Tension-Free Vaginal Obturator Tape (TVOT) - April 30, 2003 - Meeting Report

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ETH.MESH.4048515-20 - KOL Interview
ETH.MESH.4384126-65 - Clinical Evaluation Report, Gynecare TVT Tension-free Vaginal Tape / Tension-free Vaginal Tape Accessory Abdominal Guide
ETH.MESH.442825-26 - Email re: TVT Laser Mesh info
ETH.MESH.4499687-742 - An Evluation of the Gynecare TVT Secur System for the Treatment of Stress Urinary Incontinence
ETH.MESH.524746-48 - Email re: TVT Meeting with Agency
ETH.MESH.525573 - Email re: TVT Laser Cut Mesh
ETH.MESH.527118-21 - Email re: Sepulveda's Notes summary/ PLEASE DO NOT DISTRIBUTE JUST FOR INTERNAL REVIEW
ETH.MESH.5315252-65 - Final Report, PSE Accession No. 97-0197, Project No. 16672
ETH.MESH.533283-86 - Communication Plan to close TVT WORLD Registry
ETH.MESH.6479808-85 - Clinical Study Report, Evaluation of the TVT Secur System for Stress Urinary Incontinence. Study Cody 300-05-002
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Deponent [Date of Deposition]
Angelini, Laura - 09.16.13; 9.17.13; 11.14.13
Arnaud, Axel - 7.19.13; 7.20.13; 9.25.13; 11.15.12; 11.16.12
Austin, Charles E. - 8.13.15
Barbolt, Thomas - 1.7.14; 1.8.14; 8.14.13; 8.15.13; 10.9.12; 10.10.12
Batke, Boris - 8.1.13; 8.2.13
Beach, Patricia 6.17.13
Beath, Catherine - 7.11.13; 7.12.13; 3.26.12; 3.27.12; 11.8.12; 11.9.12
Brown, Allison 9.11.13
Burkley, Dan F - 5.22.13; 5.23.13; 10.2.12
Cecchini, Peter - 10.22.13; 10.23.13
Chen, Meng - 10.3.12; 10.4.12; 10.29.13; 10.30.13
Ciarrocca, Scott - 3.29.12
Courts, Paul - 6.11.15
Elbert, Katrin - 12.23.14
Gauld, Judith - 11.8.13; 4.27.12
Hart, James - 9.17.13; 9.18.13; 12.20.13
Hellhammer, Brigitte - 9.11.13; 9.12.13
Hinoul, Piet - 01.13.14; 01.14.14; 01.15.14; 6.26.13; 6.27.13; 4.5.12; 4.6.12; 9.18.12; 9.19.12
Hinoul, Piet - 04.05.2012 Deposition Testimony
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Holste, Joerg - 7.29.13; 7.30.13; 12.14.12; 12.15.12
Horton, Ronald, M. - 07.01.2015
Huniscker, Kimberly - 1.1.24; 4.1.14
Isenberg, Richard - 11.5.13; 11.6.13
Jones, Gregory R - 8.20.13
Jones, Scott - 11.15.11
Kammerer, Gene - 01.17.14; 1.28.14; 1.30.14; 6.12.13; 12.3.13; 12.5.13; 10.17.12
Kanerviko, Brian 8.23.13; 8.22.13
Kirkemo, Aaron - 01.6.14; 01.7.14; 4.18.12
Lamont, Dan - 4.3.13; 4.4.13; 9.10.13; 9.11.13; 4.4.12; 5.24.12
Lin, Susan - 3.12.13; 3.13.13; 5.2.13; 5.3.13; 8.1.13
Lisa, Bryan 12.19.11; 12.20.11; 4.25.13; 4.26.13
Luscombe, Brian - 7.29.13
Mahmoud, Ramy - 7.15.13; 7.16.13
McCoy, Sheri - 4.22.10; 10.12.12
Meek, Jonathan - 2.24.12; 9.11.12
Nager, Charles - 06.10.2014 Deposition Testimony
Nager, Charles - 6.10.14
O'Bryan, Sean - 5.18.12
Owens, Charlotte - 6.19.13; 6.20.13; 9.12.12; 9.13.12
Parisi, Paul - 6.6.13; 2.6.2013; 12.13.2011
Peebles, Rhonda - 07.16.14; 8.20.14
Robinson, David - 7.24.13; 7.25.13; 9.11.13; 3.13.12; 3.14.12; 8.23.12
Schmid, Tim - 7.31.15
Scott, Kelly M., M.D. - 1.13.2016
Selman, Renee Elayne - 6.20.13; 6.21.13

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Smith, Dan J - 2.3.14; 2.4.13; 5.15.13; 5.16.13; 6.4.13; 6.5.13; 8.20.13; 8.21.13
St Hilaire, Price - 7.11.13
Vailhe, Christophe - 6.20.13; 6.21.13
Volpe, Clifford - 2.28.12; 2.29.12
Walji, Zenobia - 3.7.12
Weisberg, Martin - 05.24.2012 Deposition Testimony
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Yale, Mark - 8.7.13; 8.8.13; 4.17.12; 5.16.12
Zaddern, Vincenzo - 3.27.12; 3.28.12

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Gynecare Prosima™ Pelvic Floor Repair System MRI Address PROS-437-10-9/12- Prosima Audio File of MRI Flashcard [1 page]
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PowerPoint- Gynecare Prosima™ Pelvic Floor Repair System PLT 12 Month Post-Launch Close-Out March 3, 2011. "Hernia Solutions US Template" [29 slides]

Other Materials

Press coverage and editorials, publications, guidelines, and statements in medical journals relating to the FDA's activities with respect to pelvic mesh products
Prosima 2011 Sales Aid- What Could a Truly Tension-Free Repair Mean for you and your Patients? [20 pages]
Prosima 522 Order
Prosima Apical Support Learning Guide [2 pages]
Prosima Brand Story & Key Message- Gynecare Proxima™ Pelvic Floor Repair System Background and Development History [16 pages]
Prosima cadaver lab invitation- Gynecare Proxima™ Pelvic Floor Repair System Cadaver Lab [1 page]
Prosima Combined Exemplar (PROC2)
Prosima E-Blast No. 1- The Proof of Success [2 pages]
Prosima Launch Sales Aid- Your Proof: Her dance class [3 pages]
Prosima Marketing Material Roll-out Letter from Kevin Forst PROS-040-10-2/12 February 16, 2010 [1 page]
Prosima MRI Flashcard 2- Gynecare Proxima™ Pelvic Floor Repair System. The first fixationless mesh system that maintains anatomical position. [2 pages]
Prosima MRI Flashcard- MRI Flashcard Learning Guide [2 pages]
Prosima NTM Opening Presentation 2011- "This Year Proxima is Personal" [8 pages]
Prosima Pelvic Model
Prosima Preceptor Confirmation- Virtual Round Table October 2010 [2 pages]
Prosima Preceptor Follow Up and Invite- Virtual Round Table October 2010 [1 page]
Prosima Prof Ed Deck 2011 [71 pages]
Prosima Prof Ed Deck Oct 09
Prosima Prof Ed Deck October 2009 [21 pages]
Prosima Revised Webinar Deck- [21 pages]
Prosima Sales Aid Training Deck- "What could a truly tension-free repair mean for you and your patients?" [5 pages]
Prosima Testimonial for NTM 2010 Video
Prosima Touch Workshop Key Takeaway [2 pages]
Prosima Trainee Confirmation- Virtual Round Table October 2010 [1 page]
Prosima Trainee Invite- Advanced Pelvic Floor Course with Gynecare Proxima Saturday, October 24, 2009 [1 page]
RANZOG and UGSA 2014 Position Statement
Reisenauer Summary Positioning Proxima- Ethicon Women's Health & Urology eClinical Compendium- Article Summary [2 pages]
SGS (2011) Executive Committee Statement Regarding the FDA Communication: Surgical placement of mesh to repair pelvic organ prolapse imposes risks
Surgical Mesh for Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence: Exuctive Summary (2011)
Testimonial Videos
The FDA and Mesh, What You Should Know as a Reconstructive Pelvic Surgeon by Lucente, V.; Cassidenti, A.; Culligan, P. White Paper Dated February 9, 2016
The King's Health Questionnaire. Linda Cardozo and Con Kelleher, 1997
TVT & TVT-O Long Term Studies (94 pages)
TVT-Secur mini-sling for stress urinary incontinence: a review of outcomes at 12 months (Plaintiff's Exhibit 2272)

Other Materials

Wound Closure Manual
Zycynski Summary Positioning Prosima- Ethicon Women's Health & Urology eClinical Compendium- Article Summary
Other
Yale Depo 8.8.13 Pages 558-569
Deposition of Aran Maree July 23, 2013 Volume II pages 344-485
Deposition of Ramy Mahmoud July 16, 2013 Volume II pages 339-733

MDL Wave Cases

Depositions
Blaivas, Jerry, M.D. (General Plaintiff Expert) - 03.02.2016
Blaivas, Jerry, M.D. TVT-S & Abbrevio (General Plaintiff Expert) - 03.03.2016
Carey, Erin (Scholl Plaintiff Expert) - 03.07.2016
Galloway, Niall T., M.D. - (Harter Plaintiff Expert) - 03.03.2016
Galloway, Niall T., M.D. - (Harter Plaintiff Expert) - 03.03.2016
Iakovlev, M.D. Vladimir (Adams Plaintiff Expert) - 03.10.2016
Iakovlev, Vladimir, M.D. (Georgilakis Plaintiff Expert) - 03.09.2016
Iakovlev, Vladimir, M.D. (Vignos-Ware Plaintiff Expert) - 03.04.2016
Kholi, M.D. Neeraj (General Plaintiff Expert)
Mays, Jimmy W., Ph.D. (General Plaintiff Expert) - 03.02.2016
Michaels, Paul (General) - 06.18.2016
Miklos, John (TVT-S General) - 04.08.2016
Ostergard, Donald (General Plaintiff Expert) - 03.09.2016
Porter, William, M.D. (Adams Plaintiff Expert) - 03.12.2016
Priddy, Duane, Ph.D. (General Plaintiff Expert) - 03.08.2016
Rosenzweig, Bruce, M.D. (Vignos-Ware Plaintiff Expert) - 03.13.2016
Shobeiri, S. Abbas, M.D.(General Plaintiff Expert) - 02.27.2016
Shobeiri, S. Abbas, M.D.(Scholl Plaintiff Expert) - 03.12.2016
Shull, Bobby (Prolift General) - 03.15.2016
Steege, John (Thomas Plaintiff Expert) - 03.16.2016
Wilson, Anne (General Plaintiff Expert) - 03.22.2016
Zipper, M.D. Ralph (General Plaintiff Expert)
Expert Reports
Blaivas, Jerry (Prolift General) - 02.01.2016
Blaivas, Jerry (TVT General) - 02.01.2016
Blaivas, Jerry (TVT-O General) - 02.01.2016
Blaivas, Jerry (TVT-S General) - 02.01.2016
Dunn, Russell (Prolift +M, Prosima General) - 01.23.2016
Elliott, Daniel (Prolift General) - Received 05.05.2016
Elliott, Daniel (TVT-S General) - 01.25.2016
Guelcher, Scott (General) - Received 05.05.2016
Iakovlev, Vladimir (General) - 01.29.2016
Klinge, Uwe (POP General) - 11.17.2015
Klinge, Uwe (SUI General) - 11.16.2015
Kohli, Neeraj (TVT-O General) - 01.2016
Margolis, Michael (TVT General) - 02.01.2016
Mays, Jimmy (General) - 01.12.2016
Mays, Jimmy (General) - 04.29.2016
Michaels, Paul (General) - 07.01.2016
Ostergard, Donald (Prolift, Gynemesh, Prolene General) - 01.31.2016
Parisian, Suzanne (General Prolift +M) - 01.30.2016
Parisian, Suzanne (TVT-S General) - Received 05.05.2016
Pence, Peggy (Notice of Adoption of Prior Reports) - 02.01.2016
Pence, Peggy (Prolift General) - 07.17.2014
Pence, Peggy (Proxima General) - 02.01.2016

MDL Wave Cases

Pence, Peggy (Supplemental Prolift General) - 03.03.2016
Pence, Peggy (Supplemental Prosima General) - 03.03.2016
Pence, Peggy (Supplemental TVT & TVT-O General) - 03.02.2016
Pence, Peggy (TVT General) - 10.14.2013
Plaintiff expert reports and materials cited in Wave general reports of Elliott, Miklos, Rosenzweig, Margolis, Blaivas, Shull, Weber, Zipper and Ostergard
Plaintiffs' Wave general expert reports and materials cited
Priddy, Duane (General) - Received 05.05.2016
Rosenzweig, Bruce (General) - 06.09.2014
Rosenzweig, Bruce (Huskey/Edwards) - 02.21.2014
Rosenzweig, Bruce (Lewis/Brown) - 10.14.2013
Rosenzweig, Bruce (MDL Design Defect) - 08.24.2015
Rosenzweig, Bruce (Proxima General) - 02.01.2016
Rosenzweig, Bruce (Ramirez) - 04.24.2015
Rosenzweig, Bruce (TVT, TVT-O Notice of Adoption of Prior Reports) - 12.15.2015
Rosenzweig, Bruce (TVT-S General) - 01.22.2016
Shull, Bobby L. - (Proxima General) - 02.01.2016
Weber, Anne (Prolift General) - 02.01.2016
Wilson, Anne (TVT General) - Received 05.05.2016
Zipper, Ralph (Prolift General) - 01.31.2016